PATENT
Docket No.: 33915-05001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Quaid		
Serial No.	:	09/413,887	**Group Art Unit**	:
Filed	:	October 6, 1999	**Examiner**	:
For	:	***Mammary Implant Having Shell With Unitary Rough Textured Outer Layer***		

RESPONSE TO NOTICE UNDER 37 CFR 1.251
PENDING APPLICATION

Mail Stop Reconstruction
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached herewith are copies of the following documents from applicant's file of the above-identified application:

1. Reissue Patent Application Transmittal (2 sheets, dated October 6, 1999), with attached Fee Transmittal Reissue Patent Application;
2. Declaration under 37 CFR 1.175 for Reissue Patent Application (3 sheets, dated October 5, 1999);
3. Specification and Claims (17 sheets);
4. Asset of Assignee and Offer to Surrender (1 sheet, dated October 5, 1999);
5. Copy of check;
6. Request for Abstract of Title (1 sheet, dated October 6, 1999);
7. Statement under 37 CFR 3.73(b) with attachments (4 sheets, dated October 6, 1999);
8. Letter to Official Draftsman (1 sheet, dated October 6, 1999);
9. Copies of Original Figures (4 sheets);
10. Power of Attorney (1 sheet, dated October 5, 1999);

11. Information Disclosure Statement (2 pages) with PTOForm 1449 (3 pages, dated October 6, 1999);

12. References cited on 1449's

13. Filing Receipt (11/17/99);

14. Fee Address Indication Form (1 sheet, dated November 6, 2000);

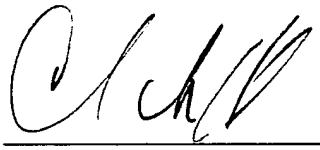
15. Statement under 37 CFR 3.73(b) (1 sheet, dated November 6, 2000);

16. Revocation of Power of Attorney (1 sheet, dated November 6, 2000);

17. Certificate of Facsimile Transmission (1 sheet, dated July 17, 2003);

18. Resubmission of Revocation of Power of Attorney (10 sheets, dated July 17, 2003);

Respectfully submitted,
Milbank, Tweed, Hadley & McCloy, LLP



April 26, 2004

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PATENT
Docket No.: 33915-05001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	QUAID			
Serial No.	:	09/413,887	**Group Art Unit**	:	3738
Filed	:	October 6, 1999	**Examiner**	:	TBA
For	:	***SPEECH SYNTHESIS USING MULTI-MODE CODING WITH A SPEECH SEGMENT DICTIONARY (AS AMENDED)***			

EXPRESS MAIL CERTIFICATE

Mail Stop Reconstruction
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I hereby certify that this correspondence is being deposited with the United States Postal Service, with sufficient postage, as Express Mail (Label No. EV 252568676 US) in an envelope addressed to: Mail Stop Reconstruction, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 26, 2004:

Respectfully submitted,
Milbank, Tweed, Hadley & McCloy, L.L.P.

Teresita Santos

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REISSUE PATENT APPLICATION TRANSMITTAL

Docket No.	:	35871/MAK/M479
Inventor(s)	:	Joel Quaid
Original Patent No.	:	5,674,285
Original Patent Issue Date *(Month/Day/Year)*	:	October 7, 1997
Title	:	MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER
Express Mail Label No.	:	EM068927420US

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Date: October 6, 1999

APPLICATION FOR REISSUE OF UTILITY PATENT

1. Application Elements

- X Fee Transmittal Form *(Submit an original and a duplicate for fee processing)*
- X Specification and Claims
- X Reissue Declaration *(37 CFR 1.175)*
- X Drawing(s) (proposed amendments, if appropriate)

2. Original U.S. Patent

- X Offer to Surrender Original Patent (37 CFR 1.178)
- ___ Ribboned Original Patent Grant
- ___ Affidavit/Declaration of Loss
- X Title Report
  - ___ Enclosed
  - X Request and fee (37 CFR § 1.19(b)(4)

3. Original U.S. Patent currently assigned?

- X Yes ___ No

(If Yes, check applicable box(es))

- X Written Consent of all Assignees
- X 37 CFR 3.73(b) Statement

4. Accompanying Application Parts

- X Power of Attorney
- X Transfer drawings from Patent File
- ___ Foreign Priority Claim *(35 USC 119)(if applicable)*
- ___ English Translation of Reissue Oath/Declaration *(if applicable)*
- X Information Disclosure Statement (IDS)/PTO-1449
  - X Copies of IDS citations
- ___ Small Entity Statement(s)
- ___ Statement filed in prior application, status still proper and desired
- X Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
- ___ Other

REISSUE PATENT APPLICATION TRANSMITTAL

Docket No.: 35871/MAK/M479

5. CORRESPONDENCE ADDRESS

CHRISTIE, PARKER & HALE, LLP, P.O. BOX 7068, PASADENA, CA 91109-7068

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____
Marc A. Karish
Reg. No. P44,816
626/795-9900

MAK/vfg

FEE TRANSMITTAL
REISSUE PATENT APPLICATION

DATE: October 6, 1999

Docket No.	:	35871/MAK/M479
Inventor(s)	:	Joel Quaid
Original Patent No.	:	5,674,285
Original Patent Issue Date	:	October 7, 1997
Title	:	MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER

FEE CALCULATION

Applicant Status: Applicant is a **large** entity.

CLAIMS AS FILED						
		NUMBER FILED	NUMBER IN ORIGINAL PATENT	NUMBER . EXTRA	RATE	BASIC FEE
A	TOTAL CLAIMS	25	7	5	5 x $9.00	$45
B	INDEPENDENT CLAIMS	9	4	6	6 x $39.00	$234
C	SUBTOTAL	SMALL ENTITY FEE = A + B LARGE ENTITY FEE = 2 X (A + B)				$558
D	BASIC FEE*	SMALL ENTITY FEE = $380.00 LARGE ENTITY FEE = $760.00				$760
E	MULTIPLE-DEPENDENT CLAIMS FEE	SMALL ENTITY FEE = $130.00 LARGE ENTITY FEE = $260.00				
F	TOTAL FILING FEE (ADD LINES C, D, AND E)					$1,318

METHOD OF PAYMENT

__X__ Payment Enclosed: Check for $1,318

__X__ The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required during the **entire pendency** of the application to Deposit Account No. 03-1728. Please show our docket number with any charge or credit to our Deposit Account. **A copy of this letter is enclosed.**

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____

Marc A. Karish
Reg. No. P44,816
626/795-9900

MAK/vfg
VFG PAS211484.1-*-10/6/99 5:10 PM

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For	:	Reissue of U.S. Patent No. 5,674,285
Patentee	:	Joel Quaid
Patent No.	:	5,674,285
Issued	:	October 7, 1997
Title	:	MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER
Docket No.	:	35871/MAK/M478

DECLARATION UNDER 37 C.F.R. 1.175 FOR REISSUE PATENT APPLICATION

Post Office Box 7068
Pasadena, CA 91109-7068
October 5, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Commissioner:

I, Joel Quaid, hereby declare that I am a citizen of the United States of America and reside at 350 Woodley Drive, Santa Barbara, California 93108. I believe I am the original, first, and sole inventor of the subject matter described and claimed in Patent No. 5,674,285, granted October 7, 1997, for which a reissue patent is sought on the invention entitled MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER, the specification of which is attached hereto. The application for patent was filed on December 12, 1995 as application Serial No. 08/570,802.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, in both the original patent and the application for reissue.

I acknowledge the duty to disclose information known to me to be material to the examination of this application, in accordance with Title 37, Code of Federal Regulations, section 1.56(a).

I believe the above-referenced original patent to be partially inoperative by reason that the claims of the original patent were erroneously and inadvertently narrowed during prosecution beyond what was needed to distinguish over the cited prior art. This inadvertence caused the issued claims to be narrower in scope than what I had a right to claim.

Specifically, claims 1, 3, 5 and 6, the four independent claims that issued in the original patent are directed to an implantable mammary device having a substantially homogeneous silicone elastomer flexible shell of unitary construction comprising a group of "cells varying in diameter from about 10 microns to about 600 microns." In claims 1 and 3 the interconnected cells are "located at and near the surface to a depth of about 1800 microns." In claims 5 and 6, a first group of cells is in direct communication with the external surface and have a range of depths down to about 600 microns below the external surface and a second group of cells have a range of depths down to about 1800 microns.

These claims fail to fully define my invention because the diameter and range of depths of the cells is unduly limiting, whereas broader aspects of the invention may be practiced in the claimed combination. All that is required is that the cells be part of a unitary and homogeneous silicone elastomer flexible shell.

All errors which are being corrected in the present reissue application up to the time of filing of this declaration arose without any deceptive intention my part.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10/5/99

By _____

Joel Quaid
350 Woodley Drive
Santa Barbara, California 93108
Citizenship: U.S.A.

MAK/vfg
VFG PAS210482.1-*-10/5/99 9:16 AM

[54] **MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER**

[75] Inventor: **Joel Quaid**, Santa Barbara, Calif.

[73] Assignee: **Medical Products Development, Inc.**, Santa Barbara, Calif.

[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,007,929.

[21] Appl. No.: **570,802**

[22] Filed: **Dec. 12, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 993,463, Dec. 15, 1992, abandoned, which is a continuation of Ser. No. 634,430, Dec. 27, 1990, abandoned, which is a continuation of Ser. No. 559,973, Jul. 27, 1990, Pat. No. 5,007,929, which is a continuation of Ser. No. 361,786, May 30, 1989, abandoned, which is a continuation of Ser. No. 927,272, Nov. 4, 1986, abandoned.

[51] **Int. Cl.**[6] **A61F 2/12**

[52] **U.S. Cl.** **623/8**; 623/11

[58] **Field of Search** 623/1, 11, 12, 623/66, 7, 8

[56] **References Cited**

U.S. PATENT DOCUMENTS

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3,314,420	4/1967	Smith et al.	128/92
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5,007,929	4/1991	Quaid	623/8

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Ersek et al. "A New Arteriovenous Shunt Design", *Trans. Ameri. Soc. Artifi. Inter. Orgs.*, vol. XV, Jun. 1989, pp. 267–271.

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Pennisi. "Polyurethane–Covered Silicone Gel Mammary Prosthesis for Successful Breast Reconstruction". *Aesthetic Plastic Surgery*. vol. 9. p. 73 (1985).

Ashley. "Further Studies on the Natural–Y Breast Prosthesis". *Plastic and Reconstuctive Surgery*. vol. 45. No. 5. p. 421 (May 1970).

Primary Examiner—David Isabella
Attorney, Agent, or Firm—Christie, Parker & Hale, LLP

[57] **ABSTRACT**

A medical implant with an external surface layer of silicone elastomer and having an open-cell structure is made by applying solid particles to the external surface layer of the implant before it is cured, curing the external surface layer with the solid particles embedded therein and then dissolving the solid particles with a solvent that does not dissolve the silicone elastomer. An implant having such an external surface layer is expected to help prevent capsular contraction, to help prevent scar formation, and to help in anchoring the implant within the body.

7 Claims, 4 Drawing Sheets

MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER

CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation of application Ser. No. 07/993,463, filed Dec. 15, 1992, now abandoned, which is a continuation of Ser. No. 07/634,430, filed Dec. 27, 1990, now abandoned, which is a continuation of Ser. No. 07/559,973, filed Jul. 27, 1990, now U.S. Pat. No. 5,007,929, which is a continuation of Ser. No. 07/361,786, filed May 30, 1989, now abandoned, which is a continuation of Ser. No. 06/927,272, filed Nov. 4, 1986, now abandoned.

FIELD OF THE INVENTION

The present invention is directed to medical devices suitable for implantation and a method for making the devices. More particularly it is directed to silicone-elastomer prostheses having an open-cell texture at the outer surface and a method for making such a prostheses using soluble solid particles.

BACKGROUND OF THE INVENTION

To be suitable for implantation within the human body, a prosthesis should be made of a material that is not physically or chemically degraded or altered by contact with body fluids, that is not toxic or allergenic to human tissue and that will not excite an inflammatory or foreign body reaction. Over the years, silicone elastomers have been found to be the materials best suited for implantation within the human body, because they come the closest to realizing the above-stated requirements. For this reason, silicone elastomers have been widely used for coating cardiac pacemakers, for making implanted catheters (Irving, Hall & Rickham, *Tissue Reaction to Pure and Impregnated Silastic*, Journal of Pediatric Surgery, Vol. 6, No. 6 at 724 (December 1971)), and for making mammary prostheses. The use of silicone elastomers in the manufacture of mammary prostheses has been especially extensive.

However, despite the relative inertness of silicone elastomers, they may still provoke an inflammatory or foreign body reaction in some patients to varying degrees. When a foreign substance enters human tissues, the immediate and natural reaction of the tissues surrounding the foreign substance is to render it harmless to the rest of the body. Small foreign bodies can be disposed of by phagocytosis, but large and inert foreign bodies are encapsulated in a sheath of fibrous tissue to isolate them from surrounding tissues. Encapsulation is a defensive mechanism that occurs through a process similar to the formation of scar tissue in the healing of a wound or surgical incision. A fibrous tissue capsule will form around and completely enclose an implanted prosthesis in an intimate fashion, conforming to its respective shapes and curvatures.

Capsule formation is not a problem for the patient unless the capsule begins to contract. With an implanted mammary prosthesis, the contracture of the capsule around the prosthesis causes it to be compressed tightly and feel very hard and rigid. Ultimately, the contracted capsule assumes a nearly spherical shape. Capsular contracture causes discomfort and embarrassment to the patients who experience it and is a serious condition both from medical and aesthetic viewpoints. One way to remedy capsular contracture is to surgically remove the contracted capsule and implant and

then insert either the same or another implant, a procedure called surgical capsulotomy or capsulectomy. Alternatively, some doctors use closed capsulotomy, a method wherein force is applied to break the capsule in situ. Of course, capsular contracture can still recur.

The problem of capsular contracture is very complex and the reasons why it occurs are not yet fully understood. Nonetheless, several different approaches to avoiding capsular contraction have been investigated. One of the most popular approaches followed today involves the use of steroids. Steroids are known to possess anti-inflammatory and anti fibrinogenic properties and been observed to cause a decrease in the relative hardness of breasts implanted with mammary prostheses. However, the use of steroids can result in complications such as tissue atrophy and discoloration of the skin. Accordingly a great deal of controversy surrounds the use of steroids and their relative utility in preventing capsular contracture. Other drugs and techniques have also been suggested, but their utility has not yet been established.

Other approaches to the problem of capsular contracture have focused on the design of the implant. Examples of mammary prostheses designed to prevent or alleviate the effects of capsular contracture are disclosed in U.S. Pat. Nos. 3,189,921; 3,366,975; 3,559,214; 3,600,718; 3,934,274; 4,095,295; 4,298,997; 4,298,998; and 4,428,082. Of these, those receiving the greatest commercial acceptance are made of a flexible, thin-walled container or sac composed of a material impervious to the ingrowth of fibrous tissue, such as a silicone elastomer, to the external surface of which a thin layer of a porous or open-celled material has been adheringly applied (U.S. Pat. Nos. 3,366,975 or 3,559,214). The interior of the sac is filled with an inert material approximating the resiliency of normal mammary tissue, such as a saline solution or a silicone gel.

The porous or open-celled layer is normally composed of a polyether, polyester or polyurethane foam material. Thin layers of this type of material had been applied to the back sides of mammary prostheses so that fibrous-tissue could grow into the material and thereby anchor a prosthesis securely to the chest wall (U.S. Pat. No. 3,293,663). However, case studies conducted on mammary prostheses almost completely covered with a thin foam layer indicated that the incidence of capsular contracture was reduced by the use of such prostheses (Pennisi, *Polyurethane-Covered Silicone Gel Mammary prosthesis for Successful Breast Reconstruction*, Aesthetic Plastic Surgery, Vol. 9 at 73 (1985); Ashley, *Further Studies on the Natural-Y Breast Prosthesis*, Plastic and Reconstructive Surgery, Vol. 45, No. 5 at 421 (May 1970)). Although the cause for the reduced incidence is not fully understood, it is believed that the growth of the fibrous tissue into the open-cell layer from many directions prevents the fibrous tissue from contracting in a concerted manner. In other words, the contractions occur in many directions and tend to neutralize each other (Pennisi, supra, at 73.

However, possible problems exist with the use of polyether, polyester or polyurethane foam materials in implants. These materials apparently degrade in the body over a period of time (Brown, Lowry and Smith, *The Kinetics of Hydrolytic Aging of Polyester Urethane Elastomers*, National Bureau of Standards (July 1979); Sherman and Lyons, *The Biological Fate of Implanted Rigid Polyurethane Foam*, Journal of Surgical Research, Vol. 9, No. 3 at 167 (March 1969)). Therefore, the effectiveness of these materials for preventing capsular contracture may disappear as they degrade. When capsular contracture does

occur and the doctor chooses to surgically remove the implant. it is difficult to ensure that all of the degraded material has been removed. These materials have also been suspected of creating problems with infection and of being carcinogenic.

To avoid the potential problems with existing foam materials and still take advantage of the reduced incidence of capsular contracture attendant with the use of prostheses having a porous or open-celled outer layer. ways have been sought to make a layer of silicone elastomer having an open-cell texture. In U.S. Pat. No. 3,852,832. a mammary prosthesis is disclosed having a fixation means attached to its back side with perforations passing therethrough and ribs projecting therefrom. This fixation means is preferably to be made of a silicone elastomer. Although no method for making such a fixation means is disclosed. it is believed that it would be separately molded. Therefore. the pattern of perforations and ribs would have to be such as to allow removal from a mold. The fixation means must then be attached to the prosthesis.

Ion-beam thruster technology has also been suggested as a way to microtexture breast prostheses (Picha and Siedlak. Ion-Beam Microtexturing of Biomaterials. MD & DI at 39 (April 1984)). However. this would interject an expensive processing step into the manufacture of breast prostheses. Also. it is not clear how the prostheses will be manipulated to achieve microtexturing over the entirety of their contoured surfaces or how effective the regular pattern of a microtextured surface will be at preventing capsular contracture. Other attempts to create an open-celled texture integral to the prosthesis shell through incorporating foaming or blowing agents in the silicone elastomer have not been successful because the surface properties of the silicone elastomers prevent the bubbles formed from connecting to one another or opening at the surface.

Accordingly. a need exists for a silicone elastomer medical implant having an external surface with an open-celled texture. Additionally. a need exists for an efficient and economic method for making such a medical implant.

SUMMARY OF THE INVENTION

In the most general terms. the present invention is directed to a member comprised of silicone elastomer and having an outer layer. at least a portion of which has an open-cell structure at the surface. A method for providing an open-cell structure to a surface of a layer of silicone elastomer is also taught. This method comprises the steps of: applying solid particles to the surface before the layer is fully cured; fully curing the layer; and dissolving the solid particles with a solvent that does not dissolve the silicone elastomer to any appreciable extent. Preferably. the solid particles have a diameter ranging from about 10 microns to about 600 microns so that the resulting cells in the open-cell structure have diameters in this same range. It is also preferable. for the solid particles to be applied so as to achieve a depth within the layer ranging from a portion of one particle diameter to a multiple of many particle diameters so that the resulting interconnected cells extend down from the surface to a depth in this same range. Most preferred is a range from about one to about three times the diameter of the solid particles.

More specifically. the present invention is directed to a medical implant with an external surface layer of silicone elastomer. at least a portion of which has an open-cell structure. Such an implant can be made through a method substantially the same as the three-step method set forth

above. Preferably, the solid particles are applied to most of the external surface layer so that most of the external surface has an open-cell structure. The solid particles can also be applied in a number of ways: by sprinkling them over the external surface layer while manipulating the medical implant; by spraying them onto the external surface layer; or by dipping the medical implant into a body of the solid particles.

Even more specifically, the present invention is directed to an improved silicone-elastomer shell for a mammary prostheses, the improvement comprising: at least a portion of the external surface of the mammary prostheses having an open-cell structure. The improved method taught for making a silicone-elastomer shell for a mammary prosthesis is comprised of the steps of: dipping a supported mandrel into a silicone-elastomer dispersion to apply a final layer of silicone elastomer to a shell adhering to the mandrel; allowing the final layer to stabilize after the mandrel is removed from the dispersion; applying solid particles to the final layers volatilizing the solvent in the final layer; placing the mandrel and the shell with the final layer into an oven maintained at an elevated temperature for a period of time; dissolving the solid particles with a solvent that does not dissolve the silicone elastomer to any appreciable extent; and evaporating any excess solvent remaining on the shell.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a mandrel used to form a mammary prosthesis according to the present invention;

FIG. 2 is a rear view of the mandrel of FIG. 1;

FIG. 3 is a sectioned side view of the shell of a mammary prosthesis according to the present invention;

FIG. 4 is a rear view of the shell of a mammary prosthesis of FIG. 3;

FIG. 5 is a magnified view of the external surface of the shell of a mammary prosthesis containing soluble solid particles;

FIG. 6 is a magnified view of the external surface of the shell of a mammary prosthesis showing the open-cell structure remaining after dissolution of the solid particles;

FIG. 7 is a magnified, sectioned side view of the external surface of the shell of a mammary prosthesis containing soluble solid particles; and

FIG. 8 is a magnified, sectioned side view of the external surface of the shell of a mammary prosthesis showing the open-cell structure remaining after dissolution of the solid particles.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred embodiment of the present invention will primarily be described in the context of a mammary prosthesis because the present invention is expected to help solve the capsular contraction problem that is particularly troublesome in the implantation of mammary prostheses. However, the present invention should not be considered as limited to such a prosthesis. Instead, the teachings of the present invention should prove to be advantageous wherever capsular contraction can damage a medical implant or cause discomfort to the patient and/or wherever a medical implant is to be anchored through the ingrowth of fibrous tissue. The present invention should also prove advantageous in preventing or controlling scar formation during wound healing after many types of plastic surgery. In addition, the present invention should have general application within the field of

mammary prostheses. as it can be used with any of a wide variety of mammary prostheses.

With reference to FIG. 1. a mandrel **10** has an external configuration corresponding to that of the mammary prosthesis to be formed by it. A rear face **12** of the mandrel has a support member **14** embedded therein and extending outward therefrom. As shown in FIG. 2 the support member enters the mandrel at the center of rear face **12**. Mandrels of this type are standard in the field. They are typically made of Delrin. aluminum. stainless steel or plastics. such as teflon/nylon combinations or high density polyethylene or polyester resin. The primary consideration is that the material be inert to the solvents and process heat used in the manufacturing process.

To begin the manufacture of a mammary prosthesis. the mandrel is dipped into a silicone rubber dispersion. Many such dispersions are used in the field. Basically they contain a silicone elastomer and a solvent. The silicone elastomer is typically polydimethylsiloxane. polydiphenyl-siloxane or some combination of these two. Typical solvents include xylene or trichloromethane. Different manufacturers vary the type and amount of the ingredients in the dispersion. the viscosity of the dispersion and the solid content of the dispersion. Nonetheless. the present invention is expected to be adaptable to have utility with a wide variety of silicone rubber dispersions.

The mandrel is lowered into the dispersion while being supported by support member **14** until the mandrel is completely submerged. The mandrel is then raised out of the dispersion with a thin coating of the material adhering thereto. The solvent in this thin coating is volatilized or caused to evaporate. Normally this is accomplished by flowing air over the coated mandrel at a controlled temperature and humidity. Different manufacturers use various quantities. velocities or directions of air flow and set the temperature and humidity of the air at different values. However. the desired result. driving off the solvent. remains the same. It is also common for prostheses manufacturers to repeat this dip and volatilize procedure a number of times so that a number of layers are built up on the mandrel to reach a desired shell thickness.

It is with the application of the final layer of silicone elastomer. that the present invention departs from the existing procedures for forming prostheses. After the mandrel is raised out of the dispersion with what is to be the final layer adhering thereto. this layer is allowed to stabilize. That is. it is held until the final coating no longer flows freely. This occurs as some of the solvent evaporates from the final coating. raising its viscosity. Once the layer has stabilized. granulated solid particles are applied evenly over the entire surface. Currently the solid particles are applied manually by sprinkling them over the surface while the mandrel is manipulated. However. it is envisioned that a machine operating like a bead blaster or sand blaster could be used to deliver a steady stream of solid particles at an adequate velocity to the coating on the mandrel. Alternatively. it is envisioned that adequate methods of solid particle application can be developed based on machines that pour the solid particles or based on dipping the coated mandrel into a body of the solid particles or exposing it to a suspension of the solid particles. It is to be understood that the present invention is not intended to be restricted to any one particular method of applying particles.

This final layer. with the solid particles embedded therein. is then allowed to volatilize. After volatilization. the entire silicone elastomer shell structure is vulcanized in an oven at

elevated temperatures. The temperature of the oven is preferably kept between about 200° F. and about 350° F. for a vulcanization time preferably between about 20 minutes and about 1 hour. 40 minutes. Upon removal from the oven. the mandrel/shell assembly is placed in a solvent for the solid particles and the solid particles allowed to dissolve. When the solid particles have dissolved. the assembly is removed from the solvent and the solvent evaporated. The shell can then be stripped from the mandrel. At this point. it is preferable to place the shell in a solvent for the solid particles and gently agitate it to ensure dissolution of all the solid particles. When the shell is removed from the solvent. the solvent is evaporated.

The process described above produces a shell **16** like that shown in FIGS. **3** and **4**. The shell has a thin outer wall **18** made of silicone elastomer with an opening **20** therein at the point where support member **14** entered mandrel **12**. In addition. the outer surface of the shell is covered with open cells **22** where solid particles **24** used to be before being dissolved. FIGS. **5** and **6** provide magnified

Views of the process whereby these open cells are formed in the surface of the shell. In FIG. **5**. solid particles **24** are shown embedded across the surface of the shell. In FIG. **6**. the solid particles have been dissolved. leaving behind open spaces in the surface of the shell. When applied. some of the solid particles are partially exposed so that they can be acted upon by the solvent. These exposed solid particles also provide a way for the solvent to reach those solid particles beneath the surface to dissolve them in turn. The result can be an interconnected structure of cells. some of which are open to the surface. in the outer layer of the shell.

With reference to FIGS. **7** and **8**. a magnified side view is provided of the process whereby the open cells are formed in the surface of the shell. In FIG. **7**. the solid particles are embedded to a depth of about 0.02 inch in a shell **16** having a thickness of about 0.042 inch. In FIG. **8**. the solid particles have been dissolved away to leave behind the open cells.

The object of the solid particle application is to create the type of random. interconnected bubble structure discussed by Dr. R. E. Holmes' research study on tissue ingrowth. found in Plastic and Reconstructive Surgery. Vol. 63. at 626–633 (1979). Therefore. the solid particles preferably have diameters ranging from about 10 to about 600 microns. The particles can be applied so as to achieve a depth ranging from a portion of one particle diameter to a multiple of many particle diameters. The particles are preferably embedded in the surface of the shell to a depth of from about one to about three times the diameter of the particles. Penetration of the solid particles depends upon the size of the particles. the thickness of the final uncured layer. the viscosity of the uncured layer and the force with which the particles are applied. These parameters can be controlled to achieve the desired depth of penetration. For example. if the last layer is relatively thick and low is viscosity. less external force will be required on the solid particles to produce an acceptable foam depth.

In choosing a solid. several factors should be evaluated: (1) the solid should be economically available in the desired particle sizes; (2) the solid should be nontoxic in case some remains in the surface of the prosthesis; and (3) the solid should be readily soluble in a solvent that is economically available. nontoxic and does not dissolve the silicone elastomer. The presently preferred solid is crystalline sodium chloride which is readily available in granulated form. The presently preferred solvent is water. which readily dissolves sodium chloride and does not

dissolve silicone rubber. However, the person skilled in the art will understand that a number of solid and solvent pairs could be chosen that would more or less fulfill the above-stated requirements.

After finishing the shell according to the steps described above, the steps required to make a finished mammary prosthesis are again similar to those used by other manufacturers. First, opening **20** is patched with unvulcanized sheeting, usually made of silicone rubber. Then, if the prosthesis is to be filled with silicone gel, this gel is added and cured, the filled prosthesis packaged, and the packaged prosthesis sterilized. If the prosthesis is to be inflated with a saline solution, a one-way valve is assembled and installed, the prosthesis is post cured if required, and the prosthesis is then cleaned, packaged and sterilized. A combination mammary prosthesis can also be made wherein a gel-filled sac is positioned inside the shell to be surrounded by saline solution.

A method has been described for creating an outer layer having an open-cell structure in a silicone elastomer member. More specifically, the method can be applied to create a medical implant with an external surface layer of silicone elastomer having an open-cell structure, to create strips having a textured surface for control of scar formation, or to improve a process for making mammary prostheses. The product made by this method has also been described and is expected to have great utility in preventing capsular contraction, in preventing or controlling scar formation, and in anchoring medical implants.

If capsular contraction does occur with a medical implant made according to the method of the present invention, the doctor is more likely to be able to remove the implant intact. The textured portion of the implant will not degrade so that the doctor can be sure that all of the implant is being removed.

Scar tissue formation in the healing of a wound or surgical incision is also a process involving the growth of fibrous tissue. A visible scar results from this healing process because the fibrous tissue is aligned in one direction. However, it is often aesthetically desirable to prevent scar formation, especially in certain types of plastic surgery. A member having an open-cell structure at the surface can be placed subcutaneously within a healing wound or incision to prevent the fibrous tissue from aligning and thereby prevent scar formation. Such a member can be advantageously made according to the present invention.

It is often important to anchor medical implants against movement. Mammary prostheses are one example of implants that must be anchored. Facial implants are another example of implants that must be anchored. With facial implants it is particularly important that they be anchored securely against movement because of their prominent location. Providing such implants with an open-cell texture according to the present invention is a particularly advantageous way to ensure that they will be anchored securely.

What is claimed is:

1. An implantable mammary device comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary and homogeneous structure; and

means for filling the interior,

wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly formed interconnected cells varying in diameter from about 10 microns to about 600 microns and located at and near the surface to a depth of about 1800 microns to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

2. An implantable mammary device according to claim 1, wherein most of the external surface is rough-textured.

3. An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly-formed interconnected cells varying in diameter from about 10 microns to about 600 microns and located at and near the surface to a depth of about 1800 microns to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

4. An improved silicone elastomer shell according to claim 3, wherein most of the external surface is rough-textured.

5. An implantable mammary device comprising:

a substantially homogeneous silicone elastomer shell of unitary construction defining an interior therein; and

means for filling the interior,

wherein the shell includes a base layer of substantially homogeneous silicone elastomer and an outer layer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface and comprising a substantially homogeneous silicone elastomer, and having defined internally therein a first group of cells varying in diameter from about 10 microns to about 600 microns formed therein and a second group of cells varying in diameter from about 10 microns to about 600 microns formed therein relative to the first group, the first group being in direct communication with the external surface and having a range of depths down to about 600 microns below the external surface, and the second group having a range of depths down to about 1800 microns below the external surface, wherein the first and second groups of cells are disposed for creating an open-cell structure, wherein the first group of cells open directly to the external surface, and the second group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting ingrowth of tissue and for preventing capsular contracture.

6. An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising a shell formed of at least a base layer of silicone elastomer, and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous

structure, the shell having an external surface with at least a portion of said external surface having defined unitarily therein an open-cell structure including a first group of cells varying in diameter from about 10 microns to about 600 microns formed therein and a second group of cells varying in diameter from about 10 microns to about 600 microns formed therein relative to the first group, the first group being in direct communication with the external surface and having a range of depths down to about 600 microns below the external surface, and the second group having a range of depths down to about 1800 microns below the external surface, the first and second groups of cells creating a network of cells to achieve the open-cell structure, wherein the first group of cells open directly to the external surface and the second group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting tissue ingrowth and for preventing capsular contracture.

7. An improved silicone elastomer shell according to claim 6, wherein most of the external surface has the open-cell structure.

8. An implantable mammary device comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary and homogeneous structure; and

a filling for the interior,

wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly formed interconnected cells varying in diameter and located at and near the surface to simulate an open-cell foam for promoting ingrowth of tissue.

9. An implantable mammary device comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary and homogeneous structure; and

means for filling the interior,

wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly formed interconnected cells varying in diameter and located at and near the surface to simulate an open-cell foam for promoting ingrowth of tissue.

10. An implantable mammary device according to claim 9, wherein most of the external surface is rough-textured.

11. An implantable mammary device according to claim 9, wherein the interconnected cells vary in diameter from about 10 microns to about 600 microns.

12. An implantable mammary device according to claim 9, wherein the interconnected cells are located at and near the

surface to a depth of about 1800 microns.

13. An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising:

a substantially homogeneous silicone elastomer flexible shell of unitary construction defining an interior therein, the shell comprising at least a base layer of silicone elastomer and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, wherein the shell has defined unitarily therein a rough-textured external surface comprising randomly-formed interconnected cells varying in diameter and located at and near the surface to simulate an open-cell foam for promoting ingrowth of tissue.

14. An improved silicone elastomer shell according to claim 13, wherein most of the external surface is rough-textured.

15. An improved silicone elastomer shell according to claim 13, wherein the interconnected cells vary in diameter from about 10 microns to about 600 microns.

16. An improved silicone elastomer shell according to claim

13, wherein the interconnected cells are located at and near the surface to a depth of about 1800 microns.

17. An implantable mammary device comprising:

a substantially homogeneous silicone elastomer shell of unitary construction defining an interior therein; and means for filling the interior,

wherein the shell includes a base layer of substantially homogeneous silicone elastomer and an outer layer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface and comprising a substantially homogeneous silicone elastomer, and having defined internally therein a first group of cells varying in diameter formed therein and a second group of cells varying in diameter formed therein relative to the first group, the first group being in direct communication with the external surface, wherein the first and second groups of cells are disposed for creating an open-cell structure, wherein the first group of cells open directly to the external surface, and the second

group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting ingrowth of tissue.

18. An implantable mammary device according to claim 17, wherein the first and second groups of cells have a diameter ranging from about 10 microns to about 600 microns.

19. An implantable mammary device according to claim 17, wherein the first group of cells have a range of depths down to about 600 microns.

20. An implantable mammary device according to claim 19, wherein the second group of cells have a range of depths down to a depth of about 1800 microns.

21. An improved silicone elastomer shell for a mammary prosthesis, the improvement comprising a shell formed of at least a base layer of silicone elastomer, and an outer layer of silicone elastomer, the base layer and outer layer being vulcanized together to form a unitary homogeneous structure, the shell having an external surface with at least a portion of said external surface having defined unitarily

therein an open-cell structure including a first group of cells varying in diameter formed therein and a second group of cells varying in diameter formed therein relative to the first group, the first group being in direct communication with the external surface, the first and second groups of cells creating a network of cells to achieve the open-cell structure, wherein the first group of cells open directly to the external surface and the second group of cells communicate with the external surface only through cells which open directly to the external surface to simulate an open-cell foam for promoting tissue ingrowth.

22. An improved silicone elastomer shell according to claim 21, wherein most of the external surface has open-cell structure.

23. An improved silicone elastomer shell according to claim 21, wherein the first and second groups of cells have a diameter ranging from about 10 to about 600 microns.

24. An improved silicone elastomer shell according to Claim 21, wherein the first group of cells have a range of depths down

to about 600 microns below the external surface.

25. An improved silicone elastomer shell according to Claim 24, wherein the second group of cells have a range of depths down to about 1800 microns below the external surface.

PATENT
M479:35871

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Reissue Application for Reissue of Patent No. 5,674,285 to Joel Quaid.

LETTER TO THE OFFICIAL DRAFTSMAN

Post Office Box 7068
Pasadena, CA 91109-7068
October 6, 1999

Assistant Commissioner for Patents
Washington, D.C. 20231

Commissioner:

Please transfer the drawings from the file of U.S. Patent No. 5,674,285 entitled MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER issued October 7, 1997 to the accompanying application for reissue of Letters Patent upon approval of the reissue application.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____
Marc A. Karish
Reg. No. P44,816
626/795-9900

MAK/vfg
VFG PAS210450.1-*-10/6/99 5:08 PM

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Fig. 1

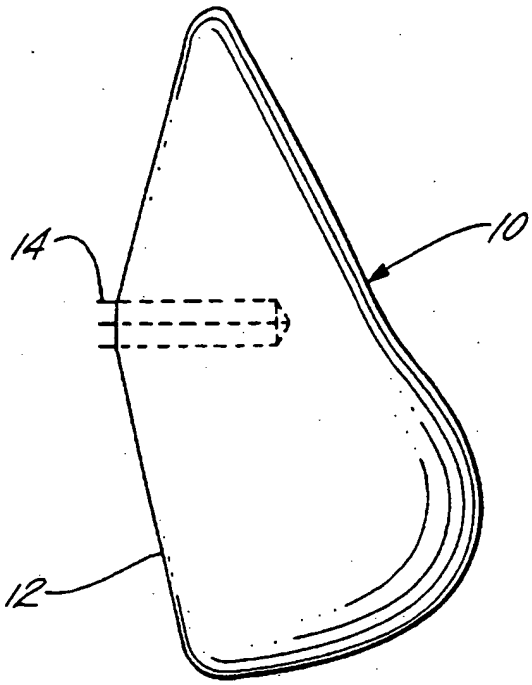


Fig. 2

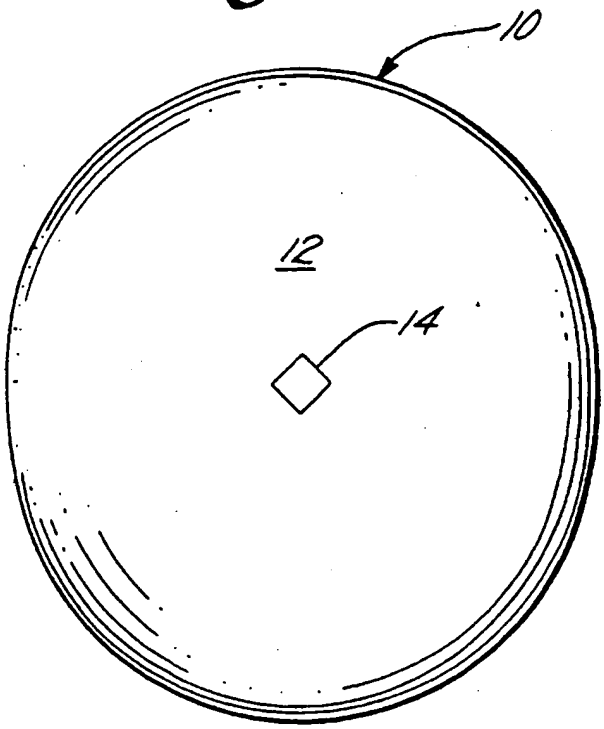


Fig. 3

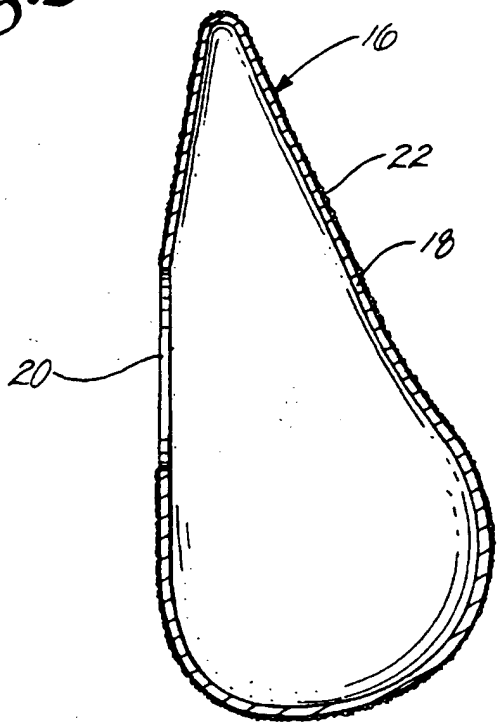


Fig. 4

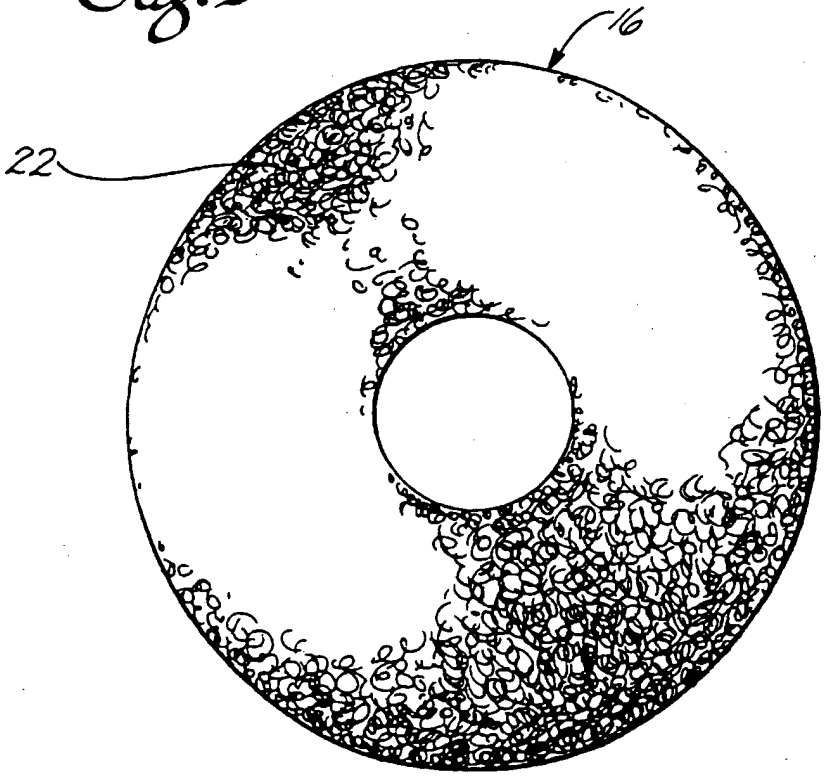


Fig. 5

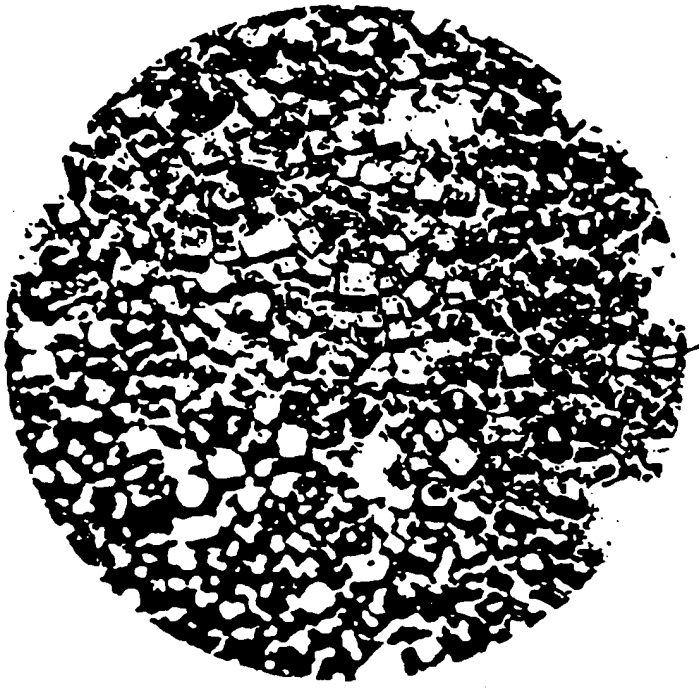


Fig. 6

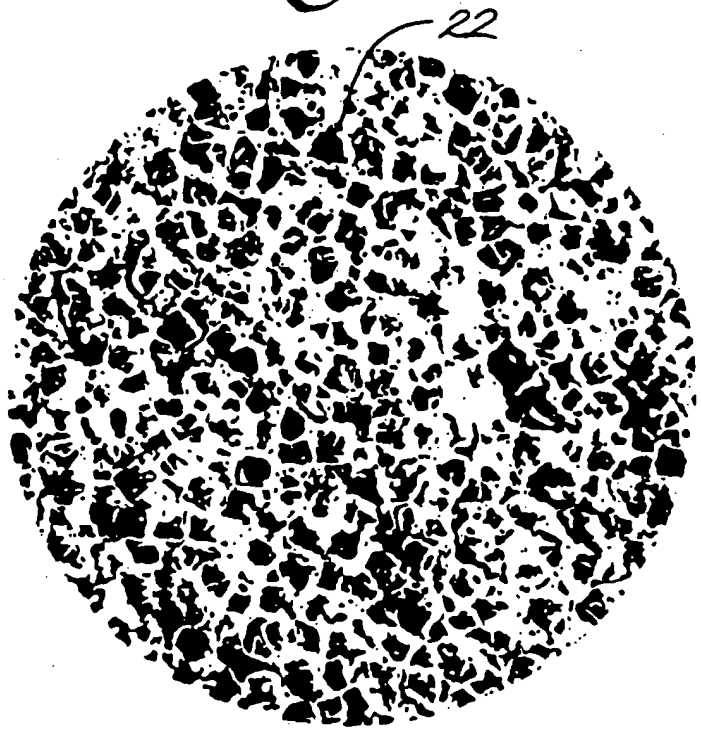


Fig. 7

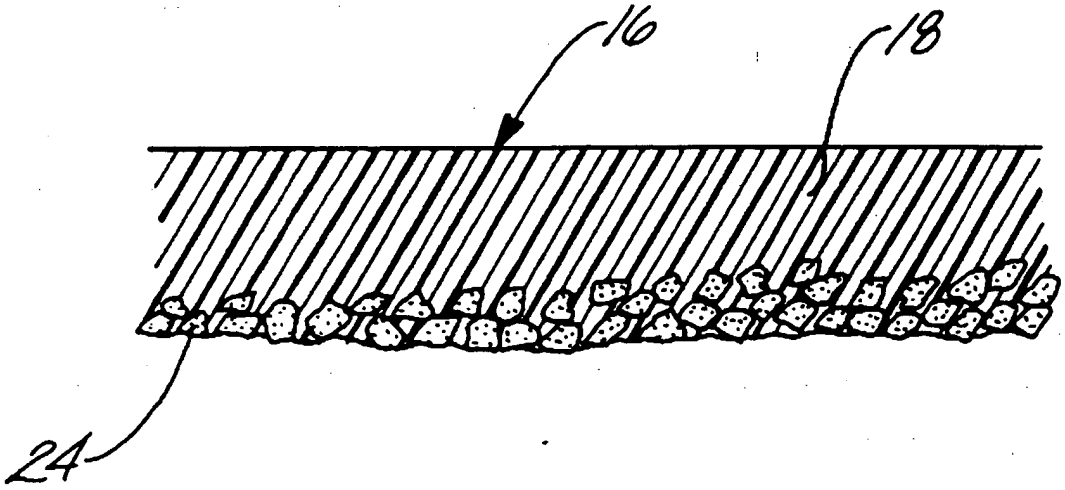
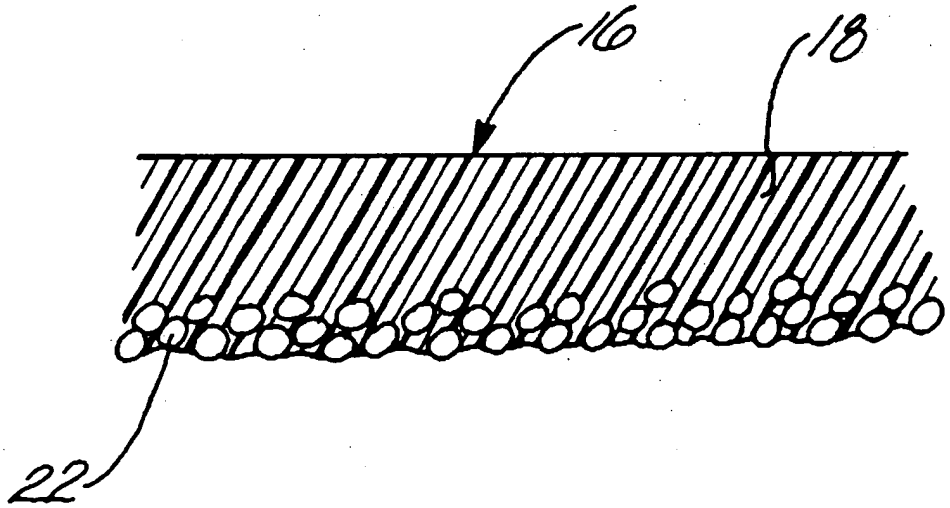


Fig. 8



PATENT
M479:35871

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ASSENT OF ASSIGNEE AND OFFER TO SURRENDER

Post Office Box 7068
Pasadena, CA 91109-7068

Assistant Commissioner for Patents
Washington, D.C. 20231

Commissioner:

Medical Products Development, Inc., assignee of the entire interest in U.S. Patent No. 5,674,285 entitled MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER issued October 7, 1997, hereby assents to the Application for Reissue of this patent for the same invention on the accompanying reissue application.

Medical Products Development, Inc., hereby offers to surrender the original Letters Patent 5,674,285.

Dated: October 5, 1999

Medical Products Development, Inc.

By _____
Peter LeVay
CFO and Treasurer

MAK/vfg
VFG PAS210479.1-*-10/5/99 3:15 PM

PATENT
35871/TJD/M479

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Joel Quaid			
Application No.	:	08/570,802	Art Unit: 3308
Filed:	:	December 12, 1995	Examiner: D. Isabella
For:	:	MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER	
Reissue of U.S. Patent No.	:	5,674,285	
Issued	:	October 7, 1997	

Assistant Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR ABSTRACT OF TITLE

Dear Commissioner:

Please have a duly certified Abstract of Title of United States Patent No. 5,674,285, issued October 7, 1997, to Medical Products Development, Inc., as Assignee of inventor Joel Quaid, prepared and placed in the official file of the above-identified application for reissue of said patent. Title in the name of Assignee was recorded on Reel 8537, Frame 0208.

Please charge the fee required by 37 C.F.R. 1.19(b)(4) to our Deposit Account No. 03-1728.

Dated: October 6, 1999

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____
Marc A. Karish
Reg. No. P44,816
626/795-9900

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant: Quaid, Joel

Application No.: 08/570,802 **Filed:** October 7, 1997

Entitled: MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER

Medical Products Developments, Inc., a California corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. [v] the assignee of the entire right, title, and interest; or

2. [ ] an assignee of an undivided part interest

in the patent application identified above by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel 8537, Frame 0208, or for which a copy thereof is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

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[ ] Additional documents in the chain of title are listed on a supplemental sheet.

[X] Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.

October 6, 1999
Date

Signature

Peter LeVay
Typed or printed name

CFO and Treasurer
Title

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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Christie, Parker & Hale, LLP

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OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TJD

JULY 23, 1997

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100452801A

CHRISTIE, PARKER & HALE, LLP
THOMAS J. DALY
P.O. BOX 7068
PASADENA, CA 91109-7068

CASE # 28701 ACTION
REMINDER DUE DATE
DEADLINE

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RECORDATION DATE: 03/10/1997

REEL/FRAME: 8537/0208
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
QUAID, JOEL

DOC DATE: 06/13/1989

ASSIGNEE:
MEDICAL PRODUCTS DEVELOPMENT, INC.
915 SAN ANTONIO CREEK ROAD
SANTA BARBARA, CALIFORNIA 93111

SERIAL NUMBER: 08570802
PATENT NUMBER:

FILING DATE: 12/12/1995
ISSUE DATE:

MARGARET LASALLE, PARALEGAL
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

07-15-1997

FORM PTO-1595
Rev. 10/95

100452801

Docket No. 28701

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Box Assignments
Washington, D.C. 20231

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Pasadena, CA 91109-7068

Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof:

1. Name of conveying party(ies):

Joel Quaid

Additional name(s) of conveying party(ies) attached: No

2. Name and address of receiving party(ies):

Name: **Medical Products Development, Inc.**

Street Address:

915 San Antonio Creek Road
Santa Barbara, California 93111

Additional name(s) & address(es) attached? No

3. Name of conveyance:

☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Other:

Execution Date: **June 13, 1989**

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)
08/570,802

B. Patent No.(s)

Additional numbers attached? No

5. Please return the recorded document and address all correspondence to:

CHRISTIE, PARKER & HALE, LLP
P.O. Box 7068
Pasadena, CA 91109-7068

Attention: **Thomas J. Daly**

6. Total number of applications and patents involved..... one

7. ☒ Total fee enclosed (37 CFR 3.41): **$ 40.00**

8. ☒ Any deficiency or overpayment of fees should be charged or credited to **Deposit Account No. 03-1728**, except for payment of issue fees required under 37 CFR § 1.18. Please show our docket number with any credit or charge to our Deposit Account.

10. ☐ Explanatory letter is enclosed.

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Date: March 5, 1997

By Thomas J. Daly

Name: Thomas J. Daly
818/795-9900; 213/681-1800

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ASSIGNMENT

WHEREAS, I, Joel Quaid a citizen of the United States of America residing at 3226 Laurel Canyon Road, Santa Barbara, California 93105 have invented certain new and useful improvements in texturing the surface of a silicone article for which I have executed an application for Letters Patent of the United States, entitled: Open-Cell, Silicone-Elastomer Medical Implant and Method for Making; and

WHEREAS, Medical Products Development, Inc., a California Corporation having its principal place of business at 3226 Laurel Canyon Road, Santa Barbara, California 93105 is desirous of obtaining the entire right, title and interest in the said improvements and the said application: Open-Cell, Silicone-Elastomer Medical Implant and Method for Making USSN: 06/927,272 Filed November 4, 1986.

NOW, THEREFORE, in consideration of the sum of one dollar ($1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said inventor, do hereby acknowledge that I have sold, assigned, transferred and set over, and by these presents do hereby severally and jointly, sell, assign, transfer and set over, unto the said Medical Products Development, Inc.

its successors, legal representatives and assigns, my respective rights, titles and interests, and the entire right, title and interest throughout the world in, to and under the said improvements, and the said application and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and applications for Letters Patent which may hereafter be filed for said improvements in any country ~~XR~~ or countries foreign to the United States, and all Letters Patent which may be granted for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty is it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said

Medical Products Development, Inc.

its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND I HEREBY covenant and agree that I will communicate to said

Medical Products Development, Inc.

its successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said

Medical Products Development, Inc.

its successors, legal representatives and assigns, to obtain and enforce proper patent protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and ~~seal~~ this 13th day of June, 1989.

J. Quaid

State of California

ss.:

County of Santa Barbara

On this 13TH day of June, 1989, before me, a Notary Public in and for the State and County aforesaid, personally appeared Joel Quaid known to me to be the person of that name, who signed and sealed the foregoing instrument, and acknowledge the same to be his free act and deed.

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PATENT
M479:35871

POWER OF ATTORNEY

The undersigned applicant of the accompanying reissue application for the reissue of Letters Patent No. 5,674,285 granted to him on October 7, 1997, entitled MAMMARY IMPLANT HAVING SHELL WITH UNITARY ROUGH-TEXTURED OUTER LAYER of which Medical Products Development Incorporated is now sole owner by assignment and on whose behalf and with whose assent the accompanying application is made hereby offers to surrender said Letter Patent.

As the named inventor, I hereby appoint the following attorneys as principal attorneys with power to appoint associate attorneys, to prosecute this application and any subsequent application based on the disclosure of this application, and to transact all business in the Patent and Trademark Office connected with this application and any such subsequent application.

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THE BIOLOGICAL FATE OF IMPLANTED RIGID POLYURETHANE FOAM

ROGER T. SHERMAN, M.D., AND HAROLD LYONS, PH.D.

USE OF SYNTHETIC MATERIALS for various surgical applications is steadily increasing, although no comprehensive laboratory investigation dealing primarily with possible mobilization, metabolic routes, excretion, storage, or possible toxic effects to the host from long-term implants of these materials has been reported.

Polyurethane foams have been utilized in a number of prosthetic materials. Some investigators have recommended rigid polyurethane foams for use in fractures and other orthopedic conditions [2, 3]. Others have demonstrated that polyurethane gives rise to foreign-body reactions [1], becomes encapsulated in connective tissue, and retards the growth of new bone. A summary of this accumulated experience with polyurethane in animal experiments indicates that opinions conflict, especially in the area of absorption and excretion of the compound [4].

This report details a long-term study of the fate of C^{14}-tagged rigid polyurethane foam inserted into the marrow cavity of the rat tibia. The polyurethane foam used in these experiments* was prepared from a mixture of toluene diisocyanates and castor oil, which is a mixed triglyceride containing about 85% ricinoleic acid and about 15% oleic acid. The average molecule contains three hydroxyl groups that lead to the production of a rigid foam. Castor oil is reacted with by an average of about one isocyanate group per hydroxyl, producing what is known as a prepolymer. The prepolymer is mixed with an aqueous solution of the catalyst and an emulsifier and rapidly sets into a rigid foam.

METHODS

Two lots of radioactive polyurethane prepolymer were prepared from C^{14}-labelled mixtures of toluene diisocyanates,† one lot being prepared from side chain–labelled material and one lot from ring-labelled material (Fig. 1).

The specific activity of the ring-labelled polyurethane was reported to be 49.5 μc. per gram and that of the side chain–labelled compound was reported as 43.6 μc. per gram.

Ring-labelled rods were prepared by pouring accurately measured amounts of prepoly-

From the Department of Surgery, University of Tennessee, and the Department of Chemistry, Southwestern at Memphis, Memphis, Tenn.

The opinions expressed are those of the authors and do not necessarily reflect the official position of the Surgeon General, U.S. Army.

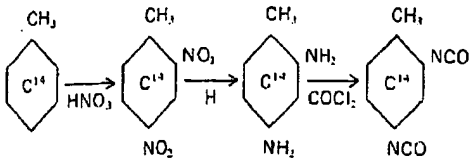
This study was supported in part by U.S. Army contract DA-49-193-MD-2099.

The rules concerning the handling of experimental animals as promulgated by the National Society for Medical Research were observed in this study.

Submitted for publication March 13, 1968.

*Ostamer, William S. Merrell Co., Cincinnati, Ohio.
†New England Nuclear Corp., Boston, Mass.

Synthesis of C^{14} ring-labelled diisocyanate:



Synthesis of side chain–labelled diisocyanate:

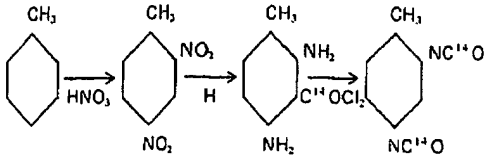


Fig. 1. Details of the C^{14}-labelled toluene diisocyanates.

mer and catalyst into a Teflon mold (Fig. 2). The plunger was quickly pushed into the die and the polyurethane foam allowed to harden for 24 hours, after which the rods were pushed from the mold by an appropriate obturator.

Side chain–labelled rods were prepared by a different process. Liberation of $C^{14}O_2$ by side-chain polymerization necessitated construction of an airtight mixing chamber with provision of an outlet trap of carbonate-free 3N NaOH to absorb the $C^{14}O_2$ evolved during the foaming reaction. Side chain–labelled prepolymer and catalyst were mixed in the chamber and placed in a Teflon mold before solidification. When the foam was completely hardened, rods were drilled from the polyurethane by a specially designed hollow bit (Fig. 3).

Specific activity of the rods was determined by oxidation to CO_2 by wet Van Slyke oxidation. The $C^{14}O_2$ was trapped in carbonate-free sodium hydroxide solution and precipitated as $BaC^{14}O_3$ by the addition of aqueous $BaCl_2$ solution. The precipitate was collected on a filter using a Tracerlab Model E-8B precipitation apparatus with E-7B rings and discs.

Samples were counted in planchets using the following Nuclear-Chicago equipment: a Model D47 gas flow counter with micromil window, a T-3 automatic valve, a Model 192-A Ultrascaler, and a Model C11013 automatic sample changer.

An experimentally determined self-absorption correction curve for $BaC^{14}O_3$ was prepared and a plot was made, normalized to unity at zero sample thickness. All samples counted were then corrected for self-absorption after correction for background activity.

The specific activity of the ring-labelled rods determined for samples was found to be 9,286 c.p.m. per milligram ± 7%. The specific activity of the side chain–labelled rods was found to be 6,250 c.p.m. per milligram ± 3%. The relatively lower specific activity of the side chain–labelled rods was due to loss of $C^{14}O_2$ from the isocyanate side chains during the polymerization and foaming process.

Holtzman-strain 200-gm. albino rats were anesthetized with ether, and amputation of

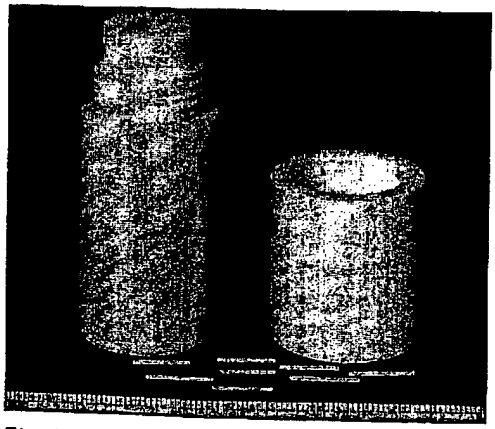


Fig. 2. Teflon mold and sample ring-labelled polyurethane rods.

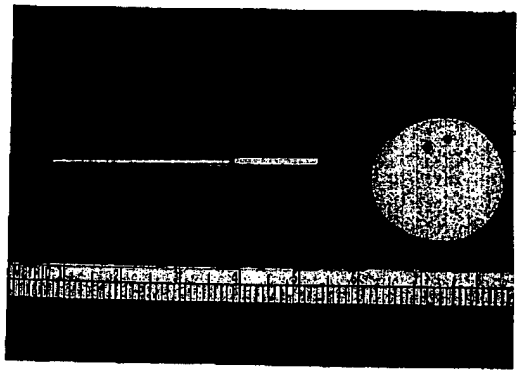


Fig. 3. Hollow bit and side chain–labelled polyurethane foam.

the left hind leg at a point 3 to 4 mm. above the tibial malleolus was accomplished, using aseptic technique. Passage of an 18 gauge hypodermic needle into the marrow canal effectively removed cancellous bone and cellular elements, allowing the implantation and impaction of the C^{14}-labelled polyurethane rods. Skin flaps were closed with a single mattress suture. The animals were permitted normal activity in cages following implantation.

Rats were sacrificed at regular intervals, and the residual activity of the labelled polyurethane implants was determined. At the time of sacrifice the tibia was amputated and oxidized using the same Van Slyke procedure employed in determination of the specific activity of the implants. There was evidence of loosening of the implant within the marrow cavity of a number of these animals at sacrifice. The samples were counted as relatively "thin" layers of $BaC^{14}O_3$ after suitable corrections were made for background activity, self-absorption, and dilution by carbonate derived from the tibia.

RESULTS

Results obtained for various times after the implant of ring-labelled rods are shown in Table 1. For each postimplant time the number of rats sacrificed and counted is shown. The calculated activity represents the theoretically calculated activity of the implant based on the weight and specific activity of the implanted rod and is subject to the same ± 7% error as the specific activity value itself. The value for activity found is that experimentally determined at the various postimplant times.

Examination of the data indicates no significant loss of implant activity through 25 weeks and only a relatively small loss through 82 weeks of the experiment.

In order to determine whether the observed decrease in activity was the result of some form of radiation self-decomposition with subsequent elimination of C^{14}, the specific activity of the rods was determined again two years after the original assay of activity. Fourteen rods which had been kept at room temperature for two years were analyzed, and the mean specific activity obtained was 8,673 c.p.m. per milligram ± 5.4%. This represents a decrease in specific activity of 6.6% since the original date of implant. Thus the self-decomposition loss will account for some, but not all, of the observed loss of activity in tibial implants, especially when it is considered that most of the samples were counted considerably less than two years after implant.

Table 1. Ring-Labelled Polyurethane Tibial Implants

Post-implant Time (wks.)	No. of Rats	Calculated Activity (total c.p.m.)	Activity Found (total c.p.m.)	Activity Gained or Lost (%)
1	5	1,166,392	1,134,533	— 2.8
4	4	1,000,101	956,400	— 4.4
9	3	804,066	748,233	— 6.9
14	1	280,501	234,200	— 16.2
17	3	739,165	669,950	— 9.4
22	3	713,165	695,044	— 2.5
25	3	809,541	858,755	+ 5.7
31	1	269,940	231,058	— 5.7
34	2	568,303	428,000	— 24.6
41	3	704,807	590,274	— 16.3
47	3	660,234	542,776	— 17.8
54	1	273,008	278,850	+ 2.1
57	3	816,988	653,806	— 20.0
63	2	557,160	495,600	— 11.1
68.5	2	493,087	348,284	— 29.3
78	2	532,128	436,198	— 18.0
82.5	2	570,160	502,785	— 11.8

Results obtained for various times after the implant of side chain–labelled polyurethane rods are shown in Table 2. Calculated activity and activity found are derived as they were for ring-labelled rods.

There are a large number of single samples reported in the side chain–labelled series because it was our decision to obtain data for as long a time after implant as possible. After some replicate sacrifices in the earlier stages to obtain a baseline for the data, implants were counted after death from natural causes.

In an attempt to determine whether the mobilized polyurethane was being stored in other body organs, the liver, spleen, pancreas,

Table 2. Side Chain–Labelled Polyurethane Tibial Implants

Post-implant Time (wks.)	No. of Rats	Calculated Activity (total c.p.m.)	Activity Found (total c.p.m.)	Activity Gained or Lost (%)
2	5	70,000	74,588	+ 6.1
14	5	79,475	61,619	— 22.3
18	4	62,625	59,202	— 5.5
23	2	33,125	31,652	— 4.4
35	1	11,875	11,625	— 2.1
48	1	13,750	9,911	— 27.9
56	1	17,500	16,524	— 5.6
61	1	16,250	13,581	— 16.4
65	2	37,500	26,723	— 28.7
70	2	38,750	19,692	— 49.2
76	4	74,375	28,381	— 61.8
85	2	28,750	16,867	— 35.0
102	1	19,375	14,632	— 24.5
115	1	15,000	10,781	— 28.1

kidneys, stomach, and intestines of a number of the sacrificed animals were homogenized in a Servall "Omni-Mixer" with the addition of small amounts of water, Triton N-101 as an emulsifier, and Dow-Corning Antifoam A to reduce foaming. From this procedure uniform homogenates could be obtained from which samples could be taken for assay of radioactivity. Normal rats which had been in the same laboratory environment for approximately the same time were taken as controls to minimize effects of contamination from atmospheric or other sources. Samples of viscera from rats with ring-labelled tibial implants ranging from 2 to 63 weeks postimplant were taken.

Only negligible amounts of activity above background level were found in most of the rats, with the exception of one rat at 63 weeks postimplant time, which had approximately 1,500 c.p.m. activity in the total visceral homogenate.

DISCUSSION

The data for the side chain–labelled rats, in general, are in agreement with those for the ring-labelled rats, with the side chain–labelled implants showing a somewhat greater rate of immobilization. Part of this difference may be attributed to differences in methods of preparation of the rods. The side chain–labelled rods were considerably more porous and cellular in nature than the ring-labelled rods and accordingly offered a greater surface for infiltration by enzymes, tissue juices, and other agents. Since the initial biological attack on these compounds could quite possibly be on the urethane linkage, which is the labelling point for the side-chain implants, these implants could be expected to show a greater loss of activity than the ring-labelled material.

It may be concluded from both ring- and side chain–labelled implants that the mobilization rate of polyurethane rods was quite slow and that approximately three-fourths of the implant material remained in situ, in some form or other, at least two years after implant.

Studies of visceral homogenates indicate that the aromatic ring from the mobilized polyurethane is apparently not stored in appreciable amounts in the organs examined.

SUMMARY

Rigid polyurethane foam was tagged both on ring and side chain by C^{14}. Rods of this material were inserted into the marrow cavity of the tibia of rats.

Loss of specific activity was followed by serial sacrifice of rats bearing ring-labelled rods over a period of 82 weeks and those bearing side chain–labelled implants over a period of 115 weeks.

Mobilization rate for both ring- and side chain–labelled implants is quite slow, and approximately three-fourths of the implant material remains in situ in some form or other at least two years after implant.

The aromatic ring from mobilized polyurethane is apparently not stored in appreciable amounts in the organs examined.

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2. Mandarino, M. P. *Clinical Osteosynthesis in Orthopedic Surgery*. Springfield, Ill.: Thomas, 1960.
3. Mandarino, M. P., and Salvatore, J. E. Polyurethane polymer; its use in fractures and diseased bone. *Amer. J. Surg.* 97:442, 1959.
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Histopathologic observations after short-term implantation of two porous elastomers in dogs

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(Received 19 December 1980; revised 19 January 1981)

This report describes the effects of pore size and material on soft tissue ingrowth of two medical-grade elastomers. Using the replamineform process, silicone rubber (SR) and bioelectric polyurethane (BEP) were rendered microporous with essentially the same microstructural pore configuration. Implants were prepared in each material having five pore size ranges: 18-25 μm, 30-45 μm, 75-95 μm, 60-120 μm, and 120-180 μm. Implants 1 cm × 1 cm × 1 mm were harvested at 1, 2, 4 and 12 weeks following subcutaneous implantation in mongrel dogs. Ingrowth of the 18-25 μm and 30-45 μm implants in both polymers consisted of histiocytes and dispersed fibrocytic proliferation during the first two weeks. By 12 weeks, the fibrocytic component had increased, but histiocytes remained the principal component of ingrown tissue. In contrast, initial ingrowth of the 75-95 μm, 60-120 μm and 120-180 μm implants showed increased fibrocytic proliferation and minimal histiocytic reaction. By 12 weeks, ingrowth into the larger-pore implants had progressed to broad bands of well organized collagenous stroma. Differences in the rate of tissue ingrowth were found to be related to both material and pore size. Less than 15% of the void spaces were infiltrated by 4 weeks in 18-25 μm and 30-45 μm SR implants, although this increased to approximately 50% by 12 weeks. In contrast, the 3 larger-pore SR implants and all pore sizes in the BEP implants were almost completely ingrown by 4 weeks.

Prosthetic implant development is linked to advances in many disciplines. The production of new biocompatible materials and improved understanding of implant systems have stimulated recent advances. These advancements are due, in part, to a delineation of the variables that enhance biocompatibility and biofunctionality.

Porosity has been found to affect favourably the performance of many implants. This is well documented in cardiovascular prostheses[1,2]. Similarly, microporous metals, polymers, and ceramics have been used successfully both experimentally and clinically for hard tissue implants. Pore sizes greater than 100 μm have been shown to enhance bone attachment and implant stabilization[3]. One goal of the continuing research effort in this field is to identify the optimal pore configuration for expedient repair of tissues and eventual restoration of normal function.

The current investigation was undertaken to evaluate the effects of pore size and biomaterial composition on the soft tissue ingrowth of two microporous polymeric materials. These polymers were fabricated in a range of pore sizes using the replamineform process[4,6], in which the skeletal structure of certain marine invertebrates serves as a template.

Presented at the Eleventh International Biomaterials Symposium, Clemson University, Clemson, South Carolina, May 1, 1979.

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MATERIALS AND METHODS

The implants used in this study were made of two medical-grade polymers: bioelectric polyurethane* (BEP) and silicone rubber† (SR). Bioelectric polyurethane is a polyester urethane with 10% elemental carbon dispersed in the polymer. A negative surface potential is generated by the elemental carbon and is reported to enhance the tissue incorporation by material; hence the designation 'bioelectric'[6].

Figure 1 (A-C) depicts the fabrication process for preparing replamineform microporous polymeric materials[4]. Skeletal precursors with the appropriate microstructural configuration were selected. One-to-one replication of the void network of the precursors was then performed, yielding implants with pores sizes 18-25 μm, 30-45 μm, 75-95 μm, 60-120 μm and 120-180 μm. Volume percent of the void network ranged from 27% to 81%. The interconnections between the pores were similar in size to the pores themselves because the precursor materials approach the characteristics of a periodic minimal surface[7].

*Research Division, Goodyear Tire and Rubber Company, Akron, Ohio, U.S.A.
†Silastic MDX-4-4210, Dow Corning Corporation, Midland, Michigan, U.S.A.

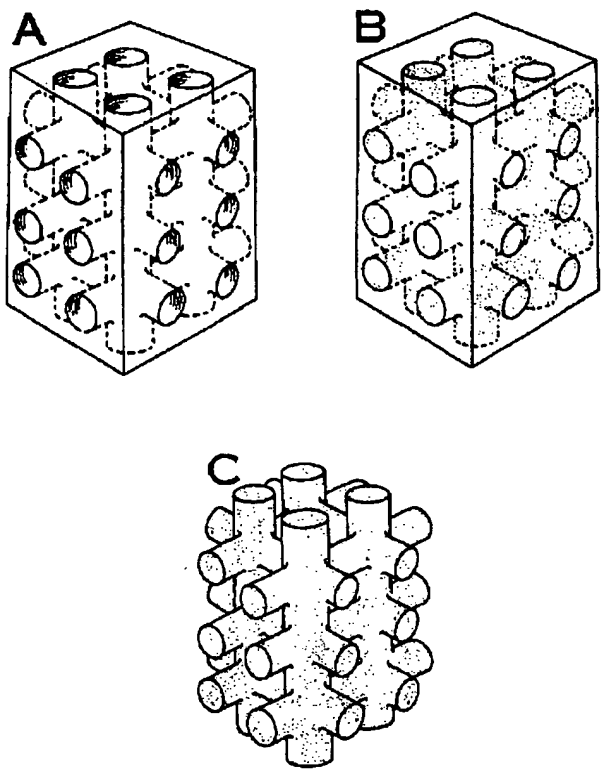

Figure 1 Replamineform fabrication process for microporous polymeric materials: (A) graphic illustration of the calcium carbonate skeletal precursor; (b) skeletal precursor infiltrated with polymer; (C) microporous polymer residual after removal of calcium carbonate.

Silicone rubber did not undergo significant volume change when cured in the precursor carbonate network. A very accurate 1:1 replication of the precursor void network was produced. In contrast, BEP underwent significant shrinkage because it is dissolved in a 55% solvent solution. When the BEP was cured in the carbonate precursor, the solvent evaporated and the BEP shrank to about 45% of its original volume. After removal of the carbonate the macroscopic dimensions and appearance of the BEP implants were identical to those of the SR implants, but the pore volume of the BEP was 55% greater than SR pore volume. Implant pore characteristics were determined by quantitative optical microscopy using grid overlay and point counting of epoxy thin sections and scanning electron photomicrograph analysis.

Materials were thoroughly cleansed in deionized water and sterilized using steam autoclave prior to implantation. BEP implants were immersed in saline during sterilization to prevent degradation[8].

Table 1 details the ratio of void network volume (V_v) to total volume (V_t), ($V_v/V_t \times 100\%$) for the materials used in this study.

Following fabrication and microstructural analysis, 80 implants 1 cm × 1 cm × 1 mm were placed subcutaneously over the sternum in mongrel dogs. Ten groups of 8 implants based on the combination of 5 pore sizes and 2 polymers were evaluated (*Table 2*). Two implants from each group were harvested at 1, 2, 4 and 12 weeks.

Upon removal, the implants were fixed in 10% formalin and stained with hematoxylin and eosin. Two cross sections from the centre of each implant were examined to determine the histological reaction to the implant including type and rate of ingrowth.

Table 1 Void network volume % for implant materials

Pore size (μm)	Void network volume %	
	Silicone rubber (no shrinkage)	Bioelectric polyurethane (55% shrinkage)
18-15	32	69
30-45	58	81
75-95	32	69
60-120	35	71
120-180	27	67

Table 2 Distribution of implants by pore size and polymer

Pore size (μm)	No of implants	
	BEP	SR
18-25	8	8
30-45	8	8
75-95	8	8
60-120	8	8
120-180	8	8

RESULTS

Striking differences in the degree and type of incorporation of the microporous implants relating to both pore size and biomaterial were observed. The histological findings concerning pore size can be consolidated into 2 broad groups: small-pore implants (18-25 μm and 30-45 μm); and large-pore implants (75-95 μm, 60-120 μm, and 120-180 μm).

Initial ingrowth of the small-pore implants consisted predominantly of fibrous exudate and a small number of fibrohistiocytes. At 1 and 2 weeks, this cellular response occupied 10-15% of the pore volume in the SR implants (*Figure 2a*) and 75-80% in the BEP implants (*Figure 2b*). By 12 weeks, a dispersed fibrocytic component had appeared in the small SR implants and the histiocytic element had increased to 50% of the pore volume (*Figure 2c*). BEP implants, however, were almost completely infiltrated at 12 weeks predominantly with histiocytes and dispersed fibrocytes (*Figure 2d*).

A different histological pattern of ingrowth occurred in the large-pore implants. Between 1 and 2 weeks, implants of both polymers became encapsulated with fibrocytic tissue spreading into the outer 2-3 pore layers (*Figure 3a, b*). By 2 to 4 weeks, fibrocytic proliferation had continued until fibrocytes and capillaries had ingrown the majority of implants. By 12 weeks, mature fibrous tissue filled the void spaces (*Figure 3c, d*).

Biomaterial-related differences in cellular response were also found. BEP implants showed marked polymorphonuclear leucocytic infiltration at 1 week. In some cases this persisted for up to 12 weeks in the central portion of the implant. In general, however, this response resolved slowly over the first 4 weeks of implantation and was replaced by a more mature, less reactive tissue. By 12 weeks, BEP implants were totally infiltrated with dense, fibrous tissue. In contrast, at 2 weeks SR implants showed scattered fibrohistiocytic ingrowth at the periphery and throughout the implant with minimal inflammatory response. By 12 weeks, SR implants were ingrown with a fibrous

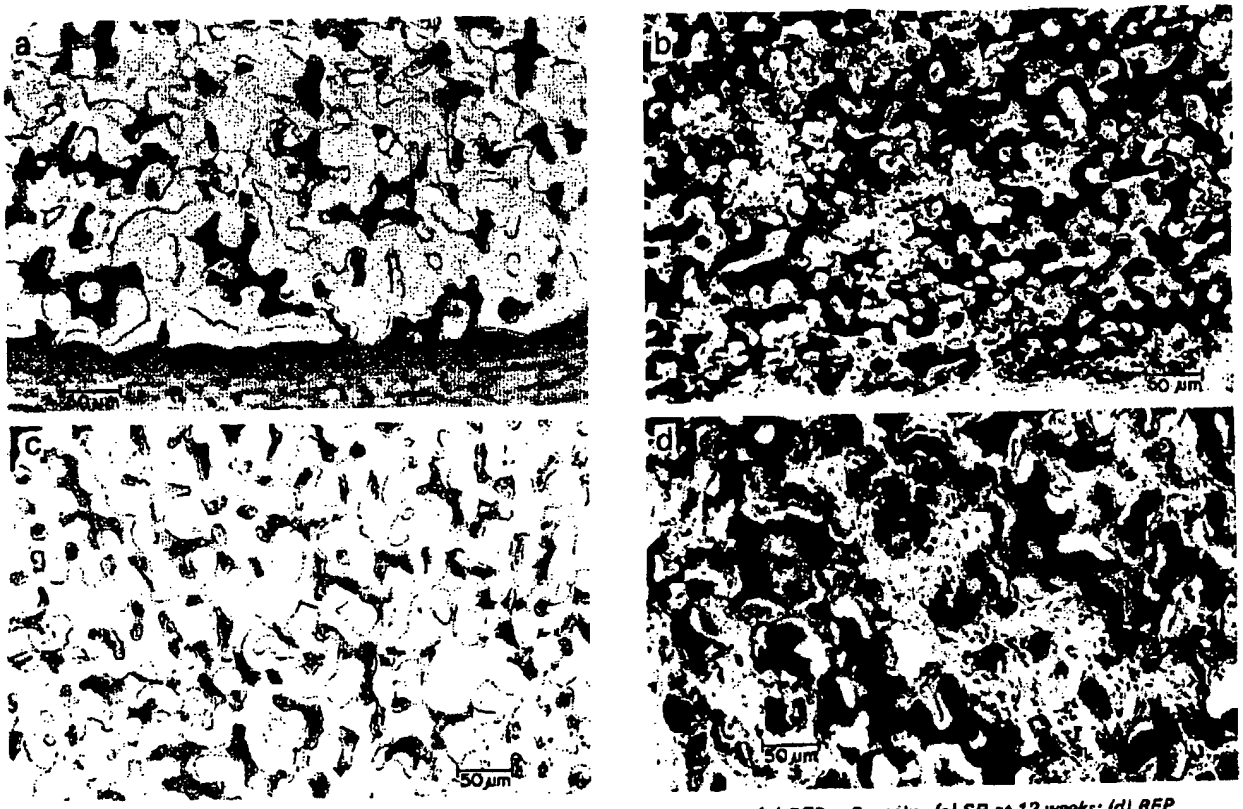

Figure 2 Histological response to small-pore implants (18-25 μm): (a) SR at 2 weeks; (b) BEP at 2 weeks; (c) SR at 12 weeks; (d) BEP at 12 weeks.

component that was homogenous and less cellular. Foreign body giant cells were found rarely in SR implants, but they were present in greater number (approximately 1/5 high-power fields) in BEP implants and were a consistent finding in the early healing phase.

Table 3 summarizes the rate and type of tissue ingrowth for implants used in this study.

DISCUSSION

Other investigators have described the tissue ingrowth achieved with various porous polymer implants. Proplast* (polytetrafluoroethylene/carbon fibre composite) implants fabricated with 100-500 μm pore size have been studied both experimentally and clinically[9,10], becoming ingrown with well vascularized soft tissue and bone when fabricated in pore sizes greater than 80 μm. Taylor and Smith[11] have investigated methyl methacrylate implants in 2 pore sizes with a mean of 42-36 μm. The larger-pore implants were found to support a well-vascularized connective tissue while those with pore sizes of less than 12 μm prevented capillary penetration. Clark *et al.*[12] studied microporous fabrications in polyester fibres, polytetrafluoroethylene, and polyurethane. Variations in response were attributed to material, pore size, and percent void volume. Our study was performed to examine these phenomena in two materials prepared by the same fabrication process.

The structural and material requirements for prostheses are dictated by function and by site of implantation. For example, vascular prostheses require flexible, blood-compatible materials whereas hard tissue prostheses require bone-compatible materials appropriate to a different biomechanical setting. Although application-dependent features are necessary, certain design principles are common to almost all implants.

Davila[13] found that most nonporous implants become encapsulated with fibrous tissue, such encapsulation preventing bonding between the prosthesis and viable tissue. He showed, however, that microporous material such as felt made from several polymers becomes ingrown with soft tissue. He stated that the 'use of fibre structure avoids large impermeable surfaces which necessitates formation of nonadherant sheets of collagenous connective tissue and prevents extensive continuous interface subject to mechanical trauma (slippage), widespread contamination if broken at any point, exudation of fluid, progressive thickening and perhaps even malignant changes.'[13]

Recognition of the relationships existing among porosity, fibrous ingrowth, and implang biocompatibility has given rise to a multitude of techniques for rendering materials microporous. Material-specific technical variations have resulted in microstructural diversity, accompanied by some confusion about the exact effects of porosity on tissue ingrowth.

Pate[14] addressed this problem by describing three parameters for porous materials: (1) porosity – the fraction of bulk volume of the material occupied by voids, (2) permeability – the degree to which the pores interconnect; and (3) pore size – the distribution of pore diameter within the implant.

Although porosity has been shown to enhance fibrous ingrowth of implants, little information on the effect of the percent of the total volume occupied by void space is

*Vitek, Inc., Houston, Texas, U.S.A.

Table 3 Rate and type of tissue ingrowth for porous elastomer implants as affected by pore size and biomaterial

Pore size	Silicone rubber				Bioelectric polyurethane			
	Early ingrowth (within 4 weeks)		Late ingrowth (within 12 weeks)		Early ingrowth (within 4 weeks)		Late ingrowth (within 12 weeks)	
	Rate	Type	Rate	Type	Rate	Type	Rate	Type
Small (18-45 μm)	10-15%	Fibro-histiocytic	50%	Fibrohistiocytic, increased fibrocytic component	75-80%	Fibrohistio-cytic, increased, poly-morpho-nuclear	100%	Fibrohistiocytic, increased fibrocytic component
Large (60-180 μm)	70-80%	Fibro-cytic	100%	Cellular, fibrous collagen and capillaries	80-80%	Fibrocytic, polymorpho-nuclear	100%	Cellular, fibrous collagen and capillaries

available. Clark *et al.*[12] studied this phenomenon by comparing the ingrowth of polyester fabrics. Void volume (V_v) in their implants was varied by modifying the open areas between fibres. The least inflammatory response was found in implants with $V_v < 10\%$. The V_v% for materials used in our study ranged from 27% to 81% – much higher than the V_v% in the implants of Clark *et al.*[12]. Although we did not evaluate materials with $V_v < 27\%$, BEP implants had a marked initial polymorphonuclear leucocytic response. This is in contrast to SR implants, which showed no inflammatory response even though their pore configuration was similar to that of the BEP implants. It is possible that the inflammatory response was due to less favourable V_v in the BEP implants, but we have attributed it to chemotactic properties of the BEP. The inflammatory response may be either related to degradation of polyurethane or to the elemental carbon dispersed in its matrix. The large surface area exposed in a uniform, microporous configuration may cause early manifestation of this problem.

Carbon itself is one of the least reactive implant materials. It is inert during tissue repair[15], thromboresistant[16], and biocompatible when tested *in vitro*[17]. One *in vivo* application, the artificial ligament, has demonstrated long-term disintegration of graphite fibre with carbon fragments migrating to peri-implant tissues and regional lymph nodes[18].

Another possible explanation for the inflammatory response encountered in our study is movement of the implant. Histiocytic response to porous implants can be influenced by mechanical stress[19]. Implants placed in mobile areas have been linked to increased infection rates and proliferation of a fibrous capsule. In fact, foreign body

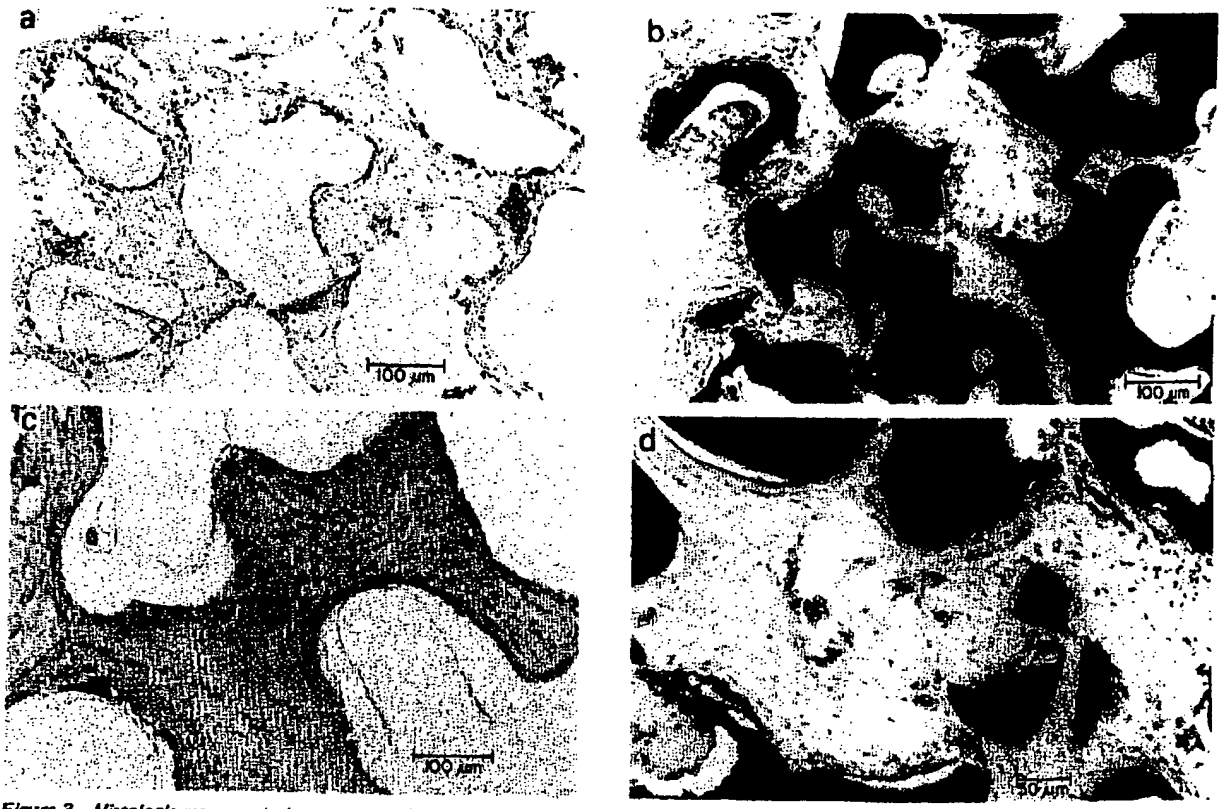

Figure 3 Histologic response to large-pore implants (60-180 μm): (a) SR at 2 weeks; (b) BEP at 2 weeks; (c) SR at 12 weeks; (d) BEP at 12 weeks.

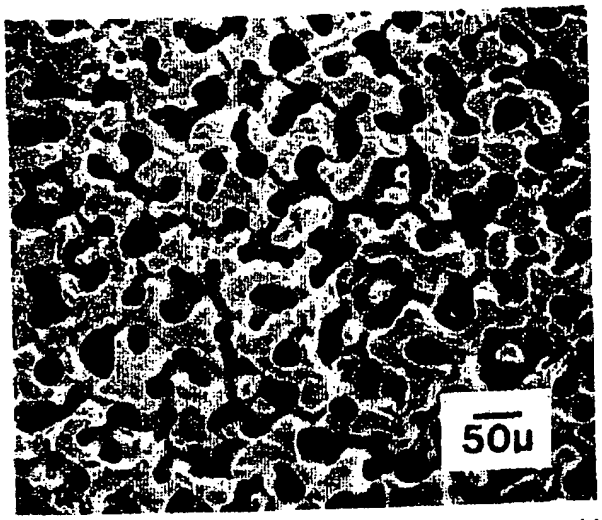

Figure 4 Scanning electron photomicrograph of precursor material from the sea urchin Heterocentrotus mammillatus. One-to-one replication of this microstructure yields an implant with pore size of approximately 25 µm and interconnections between pores of approximately 18 µm.

giant cells may be stimulated by mechanical factors alone[17]. We do not believe that mechanical stress had a major effect on our implants, however, because the inflammatory response was limited to the BEP implants.

In addition to porosity, porous implants can be characterized by the sizes of the main pores and the interconnections between the pores. *Figure 4* illustrates the nature of the porous network of the replamineform precursor materials used in our study. The relatively large diameter of the interconnections between pores in precursor materials ensures a high degree of permeability in the implants.

Although numerous materials have been studied in microporous forms, this paper focuses on polyurethane and silicone rubber. Silicone rubber has been used clinically as a solid implant material for more than 20 years. It displays many favourable qualities: low tissue reaction, bioresistance, and mouldability[20]. However, SR has not been widely used in microporous forms because fabrication techniques are not readily available. Recently, however, microporous SR has shown promise as a burn covering[21] and as a vascular prosthetic material[22,23].

Polyurethanes have had extensive biomedical applications although infrequently as implant material. Biocompatibility problems have limited their use; however, newer fabrications appear promising. Microporous forms, which are common because they are easily rendered so by a foaming process, have been studied as experimental vascular prostheses, with favorable preliminary results[24–26].

The ingrowth of open-cell polyurethane sponges fabricated as subcutaneous implants in pore ranges larger than those used in this study was reported by Salvatore *et al.*[27]. The smallest-pore-size implants (90 pores/in.; estimated 200 µm pore size) rapidly filled with dense collagenous tissue and fibrocytes displaying marked cellularity. Implants of the largest-pore-size (8 pores/in.; estimated 1500 µm pore size) filled more slowly with a loose-meshed areolar tissue that was relatively acellular. Foreign body giant cells were common in small-pore implants.

Other investigators have found a persistent round cell inflammatory response in the large-pore polyurethane samples, which were completely invaded within 3 weeks. Small-pore implants were not ingrown[12]. Increased fibrous ingrowth and decreased chronic inflammatory response were noted with decreasing pore size.

As demonstrated by our experiments and those of others, degree and type of tissue ingrowth of microporous implants can be varied by manipulating the biomaterial and the pore size. We have found that small-pore implants (18-45 µm) are ingrown predominantly with histiocytic tissue and that large-pore implants (60-180 µm) are ingrown with an organized, fibrous tissue. It is our impression that fibrous tissue provides greater structural support for soft tissue implants than does histiocytic tissue. Thus, it may be possible to manipulate the functional properties of implant systems by controlling the implant characteristics. Future investigation examining the effects of a wider range of pore sizes and biomedical materials is needed to delineate the design parameters for optimal prosthetic function.

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Aesthetic Plastic Surgery

Polyurethane-Covered Silicone Gel Mammary Prosthesis for Successful Breast Reconstruction

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Abstract. A polyurethane-covered silicone gel implant has been used by the author in 150 breast reconstructions and augmentations in the past 9 years. The results have been most gratifying with regard to breast softness, breast compressibility, and esthetics. Only 4 patients have developed a unilateral capsule contracture and firm breast. The reasons are postulated for these satisfying results. Complications have been few and very minor.

Key words: Breast reconstruction—Augmentation—Polyurethane silicone gel implant

For the past 8–9 years, this author has used a breast prosthesis that is custom-made of silicone, gel filled, and almost completely covered with a thin polyurethane sponge (polyfoam). It is oval shaped and of low profile (Fig. 1). This implant was manufactured by Heyer Schulte according to the author's suggested specifications. During this period of time, the implant has been used exclusively in 150 breast reconstructions after total mastectomy, subcutaneous mastectomy, primary and secondary augmentation, and asymmetrical hypomastia, with gratifying results. Only 4 patients developed a unilateral capsule contracture at 1 year, 2 years, 3 years, and 5 years, respectively, following surgery and all following subcutaneous mastectomy. Since these prostheses have maintained an almost uniform softness, it has never been necessary to place them below the pectoral muscle. There have been few minor complications and as the experience increased, the complications have decreased. Others have reported similar favorable experience with polyurethane-covered implants [1, 4, 5].

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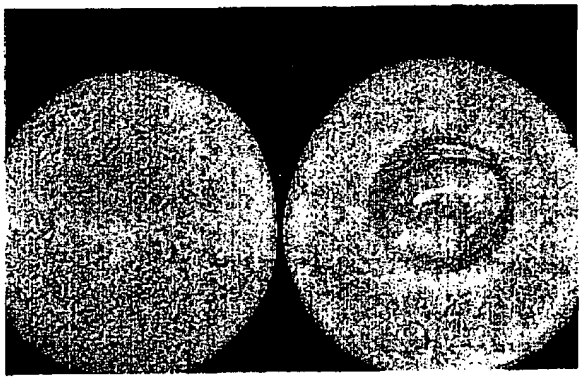

Fig. 1. Polyurethane-covered silicone gel implant depicting anterior and posterior views

This implant has a thin layer of a large-cell polyurethane sponge adhered to the surface of a gel-filled silicone implant. A central circular area on the posterior surface is exposed silicone without polyurethane which facilitates removal of the implant if it becomes necessary to do so. The large-cell nature of the polyurethane may account for the lack of capsule contracture and natural softness of the reconstructed breast. The fibroblastic proliferation into the sponge in many directions causes the fibrils to contract in many directions. This creates multivector forces which tend to neutralize each other and an esthetically soft breast results [7]. In contradistinction, when a smooth-surfaced implant is used, the fibroblasts deposit their fibrils in a circular direction, a circular contracture occurs, and the prosthesis feels firm or hard.

Fig. 2(A) A 43-year-old female before subcutaneous mastectomy for lobular carcinoma in situ and severe intraductal hyperplasia with atypia. Patient had a previous quadrectomy which revealed the extensive high-risk disease. (B) Same patient 1 year after subcutaneous mastectomy. Note wrinkling of the skin. (C) Same patient 4 years after subcutaneous mastectomy. Note definite capsule contracture of right breast

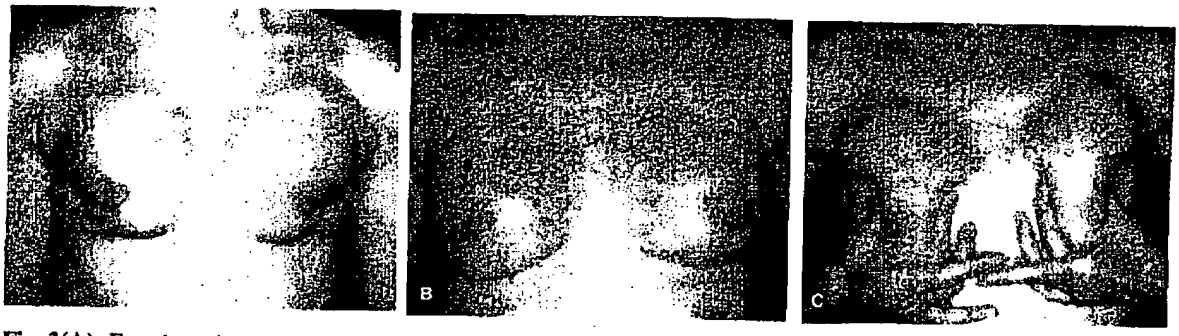

Fig. 3(A) Female patient following subcutaneous mastectomy and submuscularly placed smooth-surfaced implants. (B) Same patient 2 years after removal of submuscular smooth implants and replacement with polyfoam prostheses placed subcutaneously. (C) Same patient demonstrating softness and compressibility of the breasts with polyfoam implants

Fig. 4(A) A 48-year-old patient with bilateral severe mammary dysplasia. (B) Same patient 5 years after subcutaneous mastectomy and after bilateral nipple coring to remove remaining nipple ducts. (C) Same patient demonstrating softness and compressibility after 5 years

Microscopic foreign body reactions occur with most implantable materials and polyurethane is no exception. These have been recorded by several authors [2, 3, 11, 12]. Almost immediately after it is implanted, the polyurethane cover begins to fragment from the surface and macrophages can be found engulfing the polyurethane not unlike weeping silicone. This is a normal function of the body and need not invoke a negative criticism of the implanted material [6]. There are no published reports that polyurethane is harmful to organs or physiological functions of the human body.

A retained foreign body reaction to large pieces of polyurethane foam occurred in only 1 patient. Shortly after a subcutaneous mastectomy, the implant became exposed because of skin necrosis, and

the implant was removed. Large particles of adherent polyurethane were left behind and these acted as foreign bodies. The breast drained until all of these large particles were eventually removed. This phenomenon has not occurred when small particles of polyurethane were permitted to remain if an implant needed to be removed because of exposure or infection.

Subcutaneous Mastectomy

This type of implant has been used in 50 patients and 92 breasts. Four patients developed a unilateral capsule contracture. These occurred between 1 and 5 years after surgery (Fig. 2). In 1 patient, the contracture was observed immediately after surgery and was complete in less than 1 year. The breast required an extensive subdermal mastectomy because of close proximity of breast tissue to the skin. Little subcutaneous fat remained and the dermis was in close contact to the prosthesis. The absence of interposed fat between dermis and prosthesis could have been the cause of this contracting capsule. Even after the implant was replaced, the breast was still firm, but with 50% less firmness than the original contracture. The other 3 contractures are acceptable to the patients and have not required replacement.

All implants were placed subcutaneously and none was placed beneath the pectoral muscle. Three patients had had an unsatisfactory smooth-surfaced submuscular implant and these were removed and were replaced with polyfoam implants subcutaneously. The submuscular capsule was not excised. The results revealed a dramatic improvement (Fig. 3).

Except for the above contractures, all implants have remained remarkably soft and uniformly compressible. The only criticisms are that occasionally a slight wrinkle is noted on the surface of the skin transmitted from the underlying adherent implant; or a wrinkle fold can be palpated in some part of the margin of the implant (Fig. 4). This has not been a deterrent to patient acceptance. Wrinkling has been minimized by requesting a 10-cc overfill of gel at the time the implant was ordered.

Implant exposure will occur if the skin flap is too thin. If this occurs, the implant must be removed and the perforation allowed to heal thoroughly (3–6 months) before replacing it once again. The implant can be removed by digital dissection, but large pieces of polyurethane may adhere and must be excised. The pocket is then curetted and irrigated and the wound closed with a drain.

When the implant is replaced after 3 months, special attention must be given to the site of perforation or any area of the skin flap that may have a thin scar. In these areas some of the superficial fibers of the pectoral muscle are permitted to remain adherent to the skin flap in the course of preparing the pocket to receive the implant. Those patches of muscle reinforce the thin skin areas of scar ensuring a thicker skin flap over the prosthesis. (The implant is not placed below the pectoral muscle, although it could be if the surgeon preferred it there.)

Fig. 5. Left breast was radiated. Note skin discoloration, thickening, and contracted appearance

In 1 patient a subcutaneous mastectomy was done because of bilateral siliconoma, a positive family history of breast cancer, and bilateral severe nodularity. An invasive ductal carcinoma was found in the upper inner quadrant of one breast. This was treated by intensive radiation therapy, 5,000 rad to the entire breast and 6,000 rad to the tumor bed [8]. Within 4–12 months, the breast became increasingly fibrotic, smaller and firmer, while the skin became telangiectatic and erythematous. These were drastic radiation changes which subsequently stabilized at 1½ years after radiation therapy was completed. The integrity of the prosthesis was not altered and the overlying skin remained thickened and intact. The opposite breast remained soft and the skin was normal and healthy (Fig. 5).

This experience appears to indicate that a thorough subcutaneous mastectomy with a polyurethane-covered silicone gel implant reconstruction may not be jeopardized by intensive radiation therapy. However, the esthetic result will be significantly altered when compared with the nonirradiated breast.

Total Breast Reconstruction after Cancer Ablation

Twenty patients have had total breast reconstruction using this prosthesis. These were all reconstructed in the same manner using a superiorly based thoracoabdominal flap; the distal 2 cm were denuded and turned up beneath the prosthesis with the abdominal skin advanced upward to create the

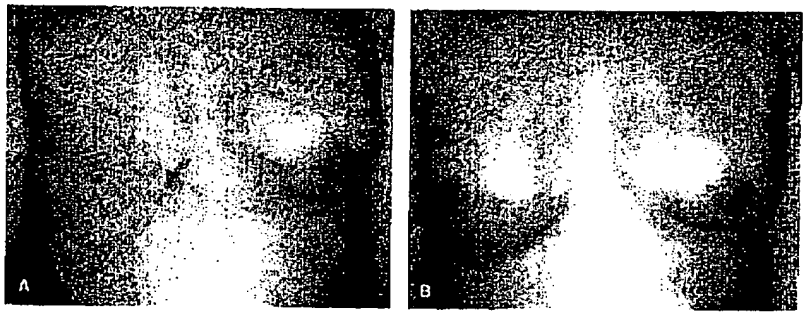

Fig. 6(A) A 49-year-old female with a right total mastectomy for cancer and a left subcutaneous mastectomy. (B) Same patient 1 year later.

Fig. 7(A) Preoperative female with ptosis of right breast and hypomastia of the left. (B) Same patient 1 year postoperative with larger volume implant in left and smaller volume in right. Left inframammary fold created by a superiorly based thoracoabdominal flap with the distal 2 cm of the flap turned upward below the prosthesis as previously described by the author [9]

inframammary fold (Fig. 6). This procedure was first described by the author in 1977 [9] and expanded on by Ryan in 1982 [10].

In all of these patients, the polyurethane-covered prosthesis was placed beneath the skin and superficial to the pectoral muscle. Once again, the skin flap was made as thick as possible. If the mastectomy scar was noted to be thin, some fibers of the pectoral muscle were permitted to adhere to the underside of the scar to provide a "blow out patch" to the scarred area.

In no instance did a capsule contracture occur and all the breasts were soft and naturally compressible. Patient and doctor satisfaction has been extremely high.

Since the prostheses are all oval shaped and a low profile, the implant is placed diagonally with the superior pole directed toward the anterior wall of the axilla but lying on the pectoral muscle. This position adds needed fullness to the tail region of the reconstructed breast providing a more esthetic and more rejuvenated breast (Fig. 4B).

Primary and Secondary Augmentations

In the early seventies, the smooth-surfaced breast prostheses were altered to a thinner silicone shell. It was anticipated that the breasts so augmented would be softer. However, the opposite occurred and, in fact, they became harder. The reason may be that the thinner shell provided less resistance against the circular capsule which contracted and produced a firm or hard breast.

In all, 16 breasts have been augmented. The longest follow-up has been 6 years and the shortest, 1½ years. The protheses were all inserted through an inframammary incision and all placed superficial to the pectoral muscle. In secondary augmentations, the previous smooth-surfaced implants were removed. In addition, the entire anterior portion of the capsule was resected and the new polyurethane-covered silicone gel implants inserted in a diagonal direction. All implants have remained so pleasingly soft that the author refuses to use any smooth surface implants in a primary or secondary augmentation.

No complications have been noted. The only criticism has been that an occasional wrinkle may be palpable in some part of the periphery of the implant. Patients are informed of this in addition to the usual complications of augmentation surgery prior to surgery and, if it occurs, patients are not disturbed by it.

This prosthesis has also been used effectively in asymmetrical hypomastia. Augmenting one or both sides produces a very esthetic symmetrical result (Fig. 7). The breasts are equally soft even when only one breast is augmented.

Conclusion

A polyurethane-covered silicone gel implant has been used by the author in 150 breast reconstruc-

tions and augmentations in the past 9 years. The results have been most gratifying with regard to breast softness, breast compressibility, and esthetics. Only 4 patients have developed a unilateral capsule contracture and firm breast. The reasons have been postulated for these satisfying results. Complications have been few and very minor.

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